

EXHIBIT 14

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Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON &)
JOHNSON TALCUM POWDER)
PRODUCTS MARKETING)
SALES PRACTICES AND) MDL 16-2738
PRODUCT LIABILITY) (FLW)(LHG)
LITIGATION)
_____)
THIS DOCUMENT)
PERTAINS TO ALL CASES)

WEDNESDAY, DECEMBER 19, 2018

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- - -

Videotaped deposition of Laura Plunkett, Ph.D., DABT, held at the Four Seasons Hotel, 999 North 2nd Street, St. Louis, Missouri, commencing at 9:12 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri & Kansas Certified Court Reporter.

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1 VIDEOGRAPHER: We are now on
2 the record.

3 My name is Jacob Arndt. I'm a
4 videographer for Golkow Litigation
5 Services.

6 Today's date is December 19,
7 2018, and the time is 9:12 a.m.

8 This deposition is being held
9 in St. Louis, Missouri, In Re: Johnson
10 & Johnson Products Marketing Sales
11 Practices, for the United States
12 District Court for the District of
13 New Jersey.

14 The deponent is Dr. Laura
15 Plunkett.

16 Will counsel please identify
17 themselves?

18 MR. MEADOWS: Ted Meadows for
19 plaintiffs.

20 MS. PARFITT: Michelle Parfitt
21 for the plaintiffs.

22 MR. BEATTIE: Ryan Beattie for
23 plaintiffs.

24 MR. TISI: Chris Tisi for
25 plaintiffs.

1 MR. GOLOMB: Richard Golomb for
2 plaintiffs.

3 MR. LOCKE: Tom Locke for the
4 Personal Care Products Council.

5 MS. TINSLEY: Caroline Tinsley
6 for PTI Union, LLC, and PTI Royston,
7 LLC.

8 MR. SULLIVAN: Ryan Sullivan
9 for Imerys.

10 MS. BOCKUS: Jane Bockus for
11 Imerys.

12 MR. SMITH: William Smith for
13 Johnson & Johnson.

14 MS. BRANSCOME: Kimberly
15 Branscome for Johnson & Johnson.

16 VIDEOGRAPHER: Thank you.

17 The court reporter is Carrie
18 Campbell and will now swear in the
19 witness.

20 LAURA PLUNKETT, Ph.D., DABT,
21 of lawful age, having been first duly sworn
22 to tell the truth, the whole truth and
23 nothing but the truth, deposes and says on
24 behalf of the Defendant Johnson & Johnson, as
25 follows:

1 DIRECT EXAMINATION

2 QUESTIONS BY MS. BRANSCOME:

3 Q. All right. Good morning,
4 Dr. Plunkett. I introduced myself right
5 before we started, but my name is Kimberly
6 Branscome, and I am here on behalf of Johnson
7 & Johnson.

8 Is it your understanding today
9 that you are giving your deposition for the
10 purpose of a Daubert analysis in the MDL
11 related to Johnson's baby powder?

12 A. That's my understanding, yes.
13 (Plunkett Exhibit 1 marked for
14 identification.)

15 QUESTIONS BY MS. BRANSCOME:

16 Q. I want to start by handing you
17 what I will mark as Plunkett Deposition
18 Exhibit 1.

19 Do you recognize the document
20 that I just handed you?

21 A. Yes.

22 Q. Okay. Have you seen this
23 document before?

24 A. Yes.

25 Q. All right. When was this

1 document provided to you?

2 A. Either earlier this -- this
3 week or late last week. I don't recall if it
4 was Friday or Monday.

5 Q. Okay. For the purposes of the
6 record, could you just identify what the
7 document is that I just handed you as
8 Plunkett Deposition Exhibit Number 1?

9 A. It's a notice of oral and
10 videotaped deposition for myself, dated -- I
11 don't see the date, but probably on the very
12 last -- do you need that or just -- is that
13 enough of an identification?

14 Q. That's all right.

15 Now, contained within the
16 deposition notice there is a reference to a
17 request for materials that are identified in
18 more detail in Schedule A.

19 Do you see that?

20 A. Yes.

21 Q. Have you reviewed Schedule A?

22 A. Yes.

23 Q. Did you bring any documents
24 with you in response to the request in
25 Schedule A?

1 A. The only thing that I believe
2 that I had to bring that had not already been
3 provided was additional billing since the
4 time of my last deposition.

5 Q. Okay. And is it my
6 understanding that the documentation related
7 to additional billing that you have done
8 since your prior deposition was produced
9 yesterday at the deposition in the Forrest
10 case?

11 A. That's correct.

12 Q. All right. And the information
13 contained in the documents produced at the
14 Forrest deposition yesterday, do those
15 contain an up-to-date record of the billing
16 that you have submitted for your work in
17 connection with the litigation against
18 Johnson & Johnson?

19 A. Yes, with the understanding
20 that I haven't submitted a bill for December
21 yet.

22 Q. Okay. How much time have you
23 spent working in connection with your
24 opinions in the case against Johnson &
25 Johnson related to its baby powder in the

1 month of December?

2 A. So I'm -- on all the cases that
3 I am involved in that are pending, not just
4 this deposition?

5 Q. I'll ask first all cases and
6 then we'll narrow it to the deposition.

7 A. So in all --

8 Q. I mean to the MDL, I'm sorry.

9 A. Okay. So in all cases this
10 month, probably eight hours so far, maybe
11 ten.

12 Q. Does that include the time that
13 you've spent attending deposition?

14 A. No, that's not including
15 yesterday's deposition time. I apologize. I
16 forgot about that.

17 Q. And how much of the eight to
18 ten hours that you have spent this month
19 working on these cases against Johnson &
20 Johnson, setting aside the time you spent in
21 deposition yesterday, relate to the MDL
22 specifically?

23 A. So it will probably be
24 billed -- it will be one bill for the
25 preparation time because the prep overlapped,

1 but I'll bill separately for the time I spent
2 yesterday right before the deposition and
3 then at the deposition, so...

4 Q. What did you do to prepare for
5 your deposition today?

6 A. I reviewed my reports, the
7 three reports that I filed in the litigation.
8 I had a meeting with attorneys on Monday, and
9 then we had a short meeting yesterday evening
10 because some attorneys arrived that were not
11 here on Monday.

12 And essentially went through
13 some of the documents that -- went through
14 some of the documents that I had cited in the
15 report in certain paragraphs, just to refresh
16 my memory of what they were. So if you want
17 me to tell you which paragraphs, I can do
18 that.

19 Q. I will in just a moment. Okay.

20 A. Want me to repeat that? I'm
21 sorry.

22 Q. That's all right.

23 Dr. Plunkett, you referenced
24 the fact that you reviewed specific
25 paragraphs of your expert reports in

1 preparation for today's deposition.

2 Could you identify those
3 paragraphs for me?

4 And it's helpful to you, we can
5 go ahead and mark your three expert reports,
6 if you're referring to all three.

7 A. I'm going to refer just to the
8 MDL report because that's what we're here to
9 talk about. I mean, if you want to talk
10 about what I did to get ready for yesterday
11 separately or --

12 MR. MEADOWS: Might be helpful
13 to go ahead and mark them.

14 MS. BRANSCOME: Why don't we go
15 ahead and just mark the three reports,
16 and then we can walk through.

17 (Plunkett Exhibits 2, 3 and 4
18 marked for identification.)

19 QUESTIONS BY MS. BRANSCOME:

20 Q. So, Dr. Plunkett, do you have a
21 copy of your three reports in front of you?

22 A. Yes, I do.

23 Q. Do those contain any markings,
24 highlightings or flags?

25 A. No, they don't.

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1 Q. Okay. Do you mind if we mark
2 your copies as the official records?

3 A. No, that's fine.

4 Q. So we will mark -- well, let's
5 do this in chronological order. So I am
6 marking as Plunkett Deposition Exhibit
7 Number 2 the expert report of Dr. Plunkett
8 dated October 5, 2016.

9 Could you confirm,
10 Dr. Plunkett, that that's what I marked as
11 Deposition Exhibit Number 2?

12 A. Yes, it is.

13 Q. And then we will mark as
14 Deposition Exhibit Number 3 supplemental
15 expert report of Dr. Laura Plunkett dated
16 August 29, 2018.

17 Dr. Plunkett, could you confirm
18 that I marked that as Exhibit Number 3?

19 A. Yes, that's correct.

20 Q. And then Exhibit Number 4, we
21 will mark the expert report dated
22 November 16, 2018, by Dr. Plunkett that was
23 produced in the MDL.

24 Could you confirm that I marked
25 that as Deposition Exhibit Number 4?

1 A. Yes, that's correct.

2 Q. All right. And so now back to
3 the question of you referenced the fact that
4 you looked at specific paragraphs of your
5 expert report in preparation for today's
6 deposition. If you could, using Deposition
7 Exhibit Number 4, identify which paragraphs
8 you looked at specifically in preparation for
9 the deposition.

10 A. So it wasn't the paragraphs.
11 There were certain documents in paragraphs,
12 so that's what I was referring to, so...
13 So starting in paragraph 38
14 where I'm talking about sort of the timeline
15 of information about human health hazards and
16 talc dust. So I just went back and refreshed
17 on a few of the older papers.

18 I looked again at the patent
19 documents that are cited in the first bullet.

20 I looked again at a paper by
21 Eberl, 1948, which is in the last bullet.
22 The patent documents are also there as well.

23 And that -- so that would be
24 all I pulled in that paragraph.

25 I believe that those documents

1 are also cited in paragraph 39 as well, some
2 of those same ones that are...

3 And then in Section 5 of my
4 report where I'm talking about exposure, I
5 looked again at Parmley and Woodruff. I
6 looked again at Vetner and Iturrulde and Egli
7 and Newton last night.

8 And the only other thing I
9 looked at is not cited in this report because
10 it came out after the report was filed, and
11 that was -- and I did bring a copy of that.
12 That was the risk assessment that was done in
13 Canada. Some people refer to it as -- by the
14 first author's last name, Taher, T-a-h-e-r.
15 And I may be pronouncing that wrong, but...

16 (Plunkett Exhibit 5 marked for
17 identification.)

18 QUESTIONS BY MS. BRANSCOME:

19 Q. All right. And I see that you
20 brought a copy of that document with you.
21 Just for the purposes of the record, let's
22 mark that as Plunkett Deposition Exhibit
23 Number 5.

24 Are there any markings,
25 highlightings or notations on that document?

1 A. No, there's not.

2 And then the other document I
3 looked at that was not cited in the report,
4 there is a printout from the government of
5 Canada website that talks about some
6 statements on talc, and so I printed that out
7 as well. This was published at the same time
8 that the risk assessment was published.

9 (Plunkett Exhibit 6 marked for
10 identification.)

11 QUESTIONS BY MS. BRANSCOME:

12 Q. All right. We'll mark that for
13 purposes of the record as Plunkett Deposition
14 Exhibit Number 6. We might come back to
15 those documents.

16 So returning briefly to the
17 deposition notice and the requests in
18 Schedule A, the billing information you
19 produced yesterday and then we just discussed
20 additional information with respect to that,
21 are there any other documents that you have
22 in your possession that are responsive to
23 requests identified in Schedule A that have
24 not been produced?

25 A. I don't believe so, no.

1 Everything -- I do believe that there were
2 some objections filed to this, so there's
3 some things that I did not provide based on
4 that.

5 Some of the things I don't
6 have, too. I think you asked for -- maybe
7 you didn't ask for that. Usually people ask
8 for copies of old depositions, and I don't
9 keep those. And maybe you didn't ask for
10 that, but that's usually a request.

11 Let me see.

12 Q. Okay. Now, you mentioned that
13 you met with attorneys on Monday. And who
14 was present at that meeting?

15 A. So on Monday it was
16 Mr. Meadows, sitting here. Ms. Tucker,
17 Mr. Beattie, were at the meeting on Monday.

18 Q. All right. And how long did
19 that meeting last?

20 A. Probably six hours, I guess,
21 six hours with them, and then I also did some
22 other work on my own, but...

23 Q. Okay. And then you mentioned
24 that you had another meeting last night.

25 Who was present at that

1 meeting?

2 A. So that was probably about an
3 hour, and that would have been Mr. Tisi -- or
4 maybe two hours. Mr. Tisi joined us
5 yesterday afternoon. And Mr. Golomb, too,
6 I'm sorry.

7 Q. All right. Okay. Now, looking
8 at the three reports that you have produced
9 in the litigation involving Johnson's baby
10 powder, I wanted to get an understanding of
11 how those three reports relate to one
12 another.

13 So you have the first report
14 that you produced that was dated October 5,
15 2016. I believe that was originally produced
16 in the Uhl case; is that correct?

17 A. I'm not sure the name of the
18 first case, but it was in the -- some of the
19 St. Louis cases, yes.

20 Q. All right. And when did you
21 begin work on that report?

22 A. You'd have to look at my
23 billing record, which I know was an exhibit
24 to yesterday's deposition. I believe they
25 started in 2015.

1 Q. All right. And then you
2 produced a supplemental report earlier this
3 year, on August 29, 2018, and that's been
4 marked as Deposition Exhibit Number 3,
5 correct?

6 A. Yes.

7 Q. When did you begin work on the
8 supplemental report that you produced at the
9 end of August in 2018?

10 A. I want to say -- let's see. I
11 want to say sometime in the summer. Maybe as
12 early as May, but I believe May -- May, June
13 time frame of 2018.

14 My billing would reflect that,
15 so, again, we can pull my billing. And I
16 would have called it preparation of the
17 supplemental report in my billing.

18 Q. Okay. Why did you choose to
19 draft a supplemental expert report?

20 A. So over the time I had worked
21 on different trials here in St. Louis
22 particularly, additional documents that were
23 not cited in my original report became
24 reliance materials based on their
25 presentation at trial. So there were enough

1 of those that I thought it was important to
2 add to the original report with additional
3 documents that I had reviewed over time.

4 Since October of 2016 through,
5 let's say, the summer of 2018, there were a
6 variety of additional documents that I had --
7 I had seen.

8 It was also my understanding
9 that during that time period Johnson &
10 Johnson had provided additional documents
11 that weren't provided or available to me in
12 2016, so additional discovery that was now
13 available to look at. So some of this is a
14 matter of additional evidence that wasn't
15 available when I wrote my initial -- my
16 initial report.

17 Q. All right. Now when you say
18 the additional documents became reliance
19 materials in trial, what do you mean by that?

20 A. So additional documents that we
21 refer to in trial that I use to support
22 opinions that weren't necessarily
23 specifically cited within the body of my
24 report or described within the body of my
25 report. They were likely on my larger

1 reliance list, but they weren't things that
2 were cited.

3 In other words, if you look at
4 my original report in -- when I say the body,
5 the paragraphs. I always put a reference
6 list and then I'll have Bates numbers. So
7 during trial, things that were from my larger
8 reliance list that weren't specifically
9 discussed in my report became support for
10 different opinions that -- based on questions
11 at trial.

12 Q. Okay. When you say these were
13 documents that "we" refer to at trial, you're
14 referring to yourself and attorneys
15 representing the plaintiffs?

16 A. Yes, that's correct.

17 Q. Okay. And understanding that
18 the purpose of today's deposition is focused
19 specifically on the MDL, then you produced a
20 report specific to the MDL on November 16,
21 2018, that we've marked as Exhibit 4,
22 correct?

23 A. Yes.

24 Q. When did you begin work on the
25 report that you produced specifically in the

1 MDL?

2 A. Sometime right after -- I would
3 say early fall of 2018, sometime after
4 this -- the supplemental report was filed.
5 Probably right after that.

6 Q. Okay. So is it fair to say
7 that you began work on your MDL report after
8 completing the supplemental expert report
9 that has been marked as Exhibit 3?

10 A. Yes, that's correct.

11 Q. Okay. Who was involved in the
12 drafting of the report that's been identified
13 as Exhibit 4?

14 MR. MEADOWS: Objection. Hang
15 on a second.

16 Are you asking about
17 communications between attorneys and
18 Dr. Plunkett?

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Dr. Plunkett, none of the
21 questions I will ask you here today are
22 intended to elicit information that's
23 protected by the attorney-client privilege.

24 So setting that aside, anything
25 that you understand to be privileged, I can

1 ask who the -- who was involved in the
2 drafting of the report that was produced in
3 the MDL?

4 MR. MEADOWS: Hold on just one
5 second.

6 Ask the question one more time.
7 I want to make sure we're not
8 venturing into attorney work product
9 realm here.

10 QUESTIONS BY MS. BRANSCOME:

11 Q. Dr. Plunkett, do you consider
12 the report that you have issued in the MDL
13 which is identified as Exhibit 4 to be
14 attorney work product?

15 MR. MEADOWS: Objection. Don't
16 answer that. That calls for a legal
17 conclusion, and at this point I'm
18 going to instruct you not to answer
19 questions about how the report came
20 into be.

21 MS. BRANSCOME: Are you
22 instructing her to refuse to answer
23 any questions that involve the
24 development of her expert report?

25 MR. MEADOWS: I'm instructing

1 her not to answer your last question.

2 QUESTIONS BY MS. BRANSCOME:

3 Q. Are you following your
4 attorney's instructions, Dr. Plunkett?

5 A. Yes.

6 MS. BRANSCOME: At this point I
7 would like to go off the record,
8 please.

9 VIDEOGRAPHER: Okay. We are
10 going off the record at 9:30 a.m.
11 (Off the record at 9:30 a.m.)

12 VIDEOGRAPHER: We are back on
13 the record at 9:32 a.m.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. Dr. Plunkett, other than
16 attorneys, if attorneys were involved -- I am
17 not asking questions about that -- were there
18 any individuals who assisted you in preparing
19 the report that has been marked as Exhibit 4?

20 A. There was no one that actually
21 assisted in writing the report. I do -- when
22 I did my literature searches, I had my
23 husband help me retrieve articles that I
24 identified for retrieval, but certainly there
25 was no -- he doesn't participate in the

1 actual review of articles or in drafting of
2 the report. That's all my work.

3 Q. Okay. And when you say that
4 your husband retrieved articles, was this
5 simply -- what information did you provide
6 him in order to enable him to retrieve a
7 particular article?

8 A. So we use a service in Houston
9 called Loansome Doc, which is affiliated with
10 our local medical library system and also
11 with the National Library of medicine and NIH
12 libraries. So I give him an online search
13 that I put into a clipboard. He takes that,
14 makes the request or retrieves -- some of
15 them will be free, and so he'll actually go
16 to the websites for the -- and then put them
17 into a folder for me.

18 So he does that physical part
19 of it through the computer, but he doesn't --
20 he doesn't do the searches or decide which
21 ones to retrieve. I do that.

22 Q. Okay. Did you have any
23 discussions with your husband about the
24 substantive content of the report that's
25 identified as Exhibit 4?

1 A. No.

2 Q. Does he do any evaluation --
3 for example, if you were to provide him a
4 search and it generates multiple documents by
5 a given author, does he identify additional
6 articles that you might want to consider?

7 A. Only -- he has done that, but
8 only with the streams of letters to the
9 editor. So I ask him always if I'm pulling
10 an article. Happens a lot at the New England
11 Journal of Medicine or some of the other
12 medical journals where there's pretty active
13 letter to the editor correspondence that
14 happens.

15 So I always say to him, "If
16 there's any citation to this through the
17 letter to the editor comments, would you
18 please retrieve those," and so he will do
19 that search to look for that.

20 Q. Okay.

21 A. And I'm not sure that that
22 happened in any of these articles, but I'm
23 talking my general process that we use.

24 Q. Okay. In terms of the
25 relationship of the three reports that have

1 been marked as Exhibits 2, 3 and 4 to each
2 other, what is your -- what is your position
3 with respect to opinions that you have stated
4 or language you have used in Exhibits 2 and 3
5 that may not appear in Exhibit 4?

6 A. I don't think I understand what
7 your -- what you mean by my position. Are
8 you asking --

9 MS. PARFITT: And I'll object
10 to that question.

11 THE WITNESS: Are you asking me
12 to describe -- I mean, I could
13 describe for you the overlap. I mean,
14 there's not complete overlap. Is that
15 what you're asking me or --

16 QUESTIONS BY MS. BRANSCOME:

17 Q. I am. Why don't you take a
18 shot at it and then I may narrow my question,
19 but I'm just trying to understand how the
20 reports relate to one another.

21 MR. MEADOWS: Objection.

22 THE WITNESS: So they relate to
23 each other, I would say, based on
24 timing first, because obviously the
25 first report was two years ago, and

1 then many more documents. So that's
2 how the 1 and 2 relate -- or Exhibit 2
3 and 3 relate to each other.

4 In the MDL litigation, I was
5 asked to address very specific topics
6 and things because there's a -- it's a
7 different -- I don't know all of them,
8 but there's a different set of experts
9 that work in different litigations.

10 So my role in the MDL, I
11 believe, is set out based on this
12 report, whereas in the original
13 reports I may have had -- I did have a
14 broader role in some of those cases.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. Okay. Can you describe for me
17 your understanding of your role in the MDL?

18 A. It's my understanding that I
19 have been asked to provide opinions related
20 to the -- generally the toxicology of talcum
21 powder products, including all the individual
22 constituents that make up that product; to
23 look historically back in time about what was
24 known and when about the toxic effects of
25 talc and different constituents within talc.

1 And that was sort of the -- that's been --
2 I consider that sort of the meat of what I've
3 been asked to do.

4 But separate from that, another
5 part important part of my testimony or things
6 I was asked to provide was an overview of the
7 regulatory process for cosmetics and then the
8 information that accumulated scientifically,
9 how that related to what a company is
10 required to do under the regulations in order
11 to provide consumers with appropriate
12 information about the safety of the product.
13 So kind of the regulatory opinions, I guess
14 you want to call it, that area.

15 I have sections on that, and I
16 think you can see that by the different
17 sections in my report where I set out
18 different general topics.

19 And then I was also asked to
20 address some of the issues related to how the
21 information on the safety of talc has been
22 disseminated publicly and also based on my
23 review of different internal company
24 documents, both from Johnson & Johnson -- or
25 from Johnson & Johnson, Imerys, as well as

1 the PCPC, which is the Personal Care Products
2 Council, formerly known as the CTFA, to look
3 at those interactions and how those companies
4 set about to influence the process around the
5 safety assessment of talc over the years. So
6 different activities that happened with
7 respect to the ISRTP meetings in the '90s,
8 with respect to the NTP process at different
9 points in time.

10 The CIR process, I think I
11 cover, and I also talk a little bit about
12 IARC, I believe, as well.

13 So the interactions of the
14 industry with the science and then how that
15 science ends up getting described within --
16 either to regulators or to bodies that are
17 reviewing the science related to the
18 products.

19 Q. You mentioned as one of the
20 categories that you were asked to opine about
21 in the MDL that you were looking to set about
22 the influence that companies may have exerted
23 over the regulatory process or PCPC.

24 When you began that analysis,
25 did you start with the predicate belief that

1 the companies had, in fact, influenced the
2 regulators or PCPC?

3 MR. MEADOWS: Objection.

4 THE WITNESS: Not in my -- not
5 when I first started this process. So
6 that is -- those opinions actually go
7 back into my original report. So
8 that's not something, I don't believe,
9 that was not covered in my original
10 report or even in my supplemental
11 report. I just have different -- some
12 additional documents that I have
13 reviewed.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. Okay.

16 A. And this is something when I
17 first evaluated the case and first started
18 looking at the documents, those are opinions
19 that I had formed based on my review.

20 Certainly by the time I drafted
21 the MDL report, I think if you listened to
22 my -- read my trial testimony, you understand
23 I had those opinions at the time I started
24 writing this report.

25 Q. Now, what I'd like to

1 understand next is, are there -- of the
2 topics that you just identified that you
3 understand that you're offering opinions
4 about in the MDL, which, if any, of those
5 topics are in your view new as compared to
6 the opinions that you have offered that are
7 contained in Exhibits 2 and 3?

8 MS. PARFITT: Objection.

9 THE WITNESS: So I don't think
10 any of the MDL opinions are new.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. Okay.

13 A. I think that they may have --
14 they may -- they may cite to additional
15 documents that haven't been cited to in the
16 first two reports, but I believe there's a
17 significant overlap even on the documents
18 that are cited.

19 Q. And you mentioned that your
20 role in the MDL is more narrow than the role
21 you've served in other cases.

22 What topics have you opined
23 about in other cases that you are not
24 intending to opine about in the MDL?

25 A. So I am not doing general

1 causation in the MDL, although I am indeed
2 providing opinions on certain aspects of the
3 cause and effect relationship such as -- you
4 know, I talk about biologic plausibility,
5 underlying knowledge about different
6 toxicities of the compounds over time, but
7 I'm not doing a full causation analysis in my
8 MDL report, and hopefully you see that when
9 you read the report.

10 Q. So as you sit here today,
11 Dr. Plunkett, you are not intending to offer
12 the opinion in the MDL that Johnson's baby
13 powder causes ovarian cancer; is that
14 correct?

15 A. Not in those words. I think if
16 you read my report, I talk about the
17 fact that Johnson -- it's my opinion that
18 Johnson's baby powder increases the risk of
19 cancer -- ovarian cancer, which is a
20 different assessment than the way you stated
21 it.

22 Q. All right. And it is -- as you
23 sit here today, Dr. Plunkett, it is your
24 understanding that you are not being offered
25 to give a, as you termed it, a general

1 causation opinion in the MDL, correct?

2 A. That's my understanding, yes.

3 Q. Now, you mentioned that the
4 analysis as to whether a substance increases
5 the risk of a particular outcome is different
6 than a causation analysis.

7 Can you explain to me what you
8 meant by that?

9 A. So I discussed this yesterday
10 in my deposition. There's -- there's a
11 process called risk assessment. Sometime --
12 in the area of consumer products you can also
13 refer to it as safety assessment. And then
14 there's the process of what I call general
15 causation analysis, or full causation
16 analysis.

17 So even though the types of
18 information that are considered may overlap
19 between those two, the outcome or the
20 statements or the -- the way you go about
21 assessing the information is a bit different.

22 Q. Explain to me how they're
23 different.

24 A. So in a risk assessment, the
25 process starts with setting out some basic

1 principles of, first, is there a hazard, is
2 the first step. Is there a hazard that would
3 be relevant to human health.

4 Then looking at the data and
5 determining whether that -- that body of data
6 allows you to either quantify risk in some
7 way or to qualitatively shows you that
8 there's a change in risk based on exposure to
9 the product.

10 So your statement may be as
11 simple as there's an increased risk, or you
12 can take data in a risk assessment and do a
13 quantification such as in a -- a cancer risk
14 assessment based on an animal data set. You
15 might actually calculate a cancer potency
16 factor, for example. Those kinds of things.
17 That's another application of risk
18 assessment. Same basic process but focusing
19 just, for example, on one study.

20 My human health risk assessment
21 or safety assessment, like the causation
22 analysis, does look across all kinds of data,
23 but my goal was not to analyze the data under
24 the Hill considerations, which is what I
25 would typically do, in order to go through

1 the process of making that final opinion that
2 indeed baby powder -- exposure to baby powder
3 through genital application is a cause of
4 ovarian cancer in women. That's -- to me,
5 that's a different way to go about thinking
6 about the question that you have to answer.

7 And also the -- some of the
8 data that you evaluate is evaluated a bit
9 differently. So, for example, in my
10 increase -- in my issue of increased risk, I
11 use the epidemiology as supporting evidence,
12 but I'm really focused on -- on -- more on
13 the underlying sort of the biologic
14 information that we have that identifies
15 hazard and risk. So looking at the animal
16 data, the exposure potential for the product,
17 and then using that along with what we know
18 with the human experience to characterize
19 risk.

20 Q. Is there a different level of
21 certainty required to render a causation
22 opinion than to render an opinion that
23 there's an increased risk?

24 A. I don't know that I'd describe
25 it quite that way but -- because to me it's a

1 different process. I certainly have to be
2 just as certain about what I say about risk
3 when I do a risk assessment as I do about --
4 as I do when I'm doing a causation analysis.

5 I don't -- maybe you mean
6 something else, so maybe you can -- I mean,
7 I -- I certainly use the same basic standards
8 in my mind, how I weigh evidence to do the
9 different processes, but I go about them in a
10 little bit different way when I do a risk
11 assessment versus -- versus a causation
12 analysis.

13 Q. In your view, does the strength
14 of the evidence have to be greater in order
15 to determine that an agent causes a disease,
16 for example, than it does simply to say that
17 an agent increases the risk of a particular
18 outcome?

19 MR. MEADOWS: Objection.

20 THE WITNESS: I don't think
21 I've ever thought about it that way.
22 I would say to you that strength --
23 the strength of the association is a
24 consideration under Hill that you
25 apply the epidemiology data mainly, so

1 that is a different consideration
2 under causation than you do -- as you
3 would do it in a risk assessment.

4 But the strength of the
5 evidence, it's still a judgment based
6 on your experience and training as far
7 as whether or not there is enough
8 information to be able to say that you
9 believe that there is -- enough
10 information to say that the risk is
11 increased based on that exposure and
12 those conditions and whatever the
13 toxicity profile of that compound is.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. Okay. We'll get into this more
16 a little bit later, but when you say that a
17 risk is increased, is there a threshold level
18 of increase that you need to see in order to
19 render an opinion in a court of law that an
20 agent increases the risk of a particular
21 outcome?

22 MR. MEADOWS: Objection.

23 THE WITNESS: So I need you to
24 define what you mean by threshold.

25 Are you asking me a specific

1 statistical test you would apply, or
2 what are you asking?

3 QUESTIONS BY MS. BRANSCOME:

4 Q. So understanding that for the
5 most part if you're looking at statistical
6 significance, you're looking whether the
7 confidence interval crosses 1.

8 Are you following?

9 A. Yes, I know that, yeah.

10 Q. All right. And so when you're
11 evaluating, though, whether a particular
12 substance, in this case Johnson's baby
13 powder, increases the risk of an outcome,
14 again, in this case ovarian cancer, would it
15 be sufficient for you if that increase was
16 .01 percent, for example?

17 MR. MEADOWS: Objection.

18 THE WITNESS: That doesn't make
19 sense to me, an increase of .01
20 percent, but maybe I can answer it
21 this way for you based on what you've
22 laid out there.

23 Certainly when I do a risk
24 assessment and I make it -- if I'm
25 going to make the conclusion that I

1 believe that it's my opinion to a
2 reasonable degree of scientific
3 certainty that exposure to baby powder
4 in women increases the risk of cancer,
5 I'm having to rely on -- I do rely on
6 data that allows me to draw
7 conclusions because either there's a
8 statistical significant finding found
9 or the -- there's a consistency among
10 the pattern of the data that shows
11 there's information that fits together
12 consistently. And maybe -- you want
13 me to explain what I mean by that?
14 No?

15 Whereas I think what you're
16 asking is when an epidemiologist
17 applies -- looks at a body of -- in a
18 causation analysis looks at a body --
19 and I do this, too -- looks at a body
20 of epidemiological studies and you
21 weight the studies, obviously you're
22 weighting the studies differently
23 based on whether they have shown
24 statistical significance or not,
25 right?

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1 And it isn't that it's a one to
2 one. If you have one positive and one
3 negative, that isn't how you may
4 decide to finally weight that
5 evidence, but certainly you have to
6 consider whether or not what was seen
7 or reported is showing you something
8 reliable -- or you can make a
9 statement reliably about whether or
10 not that finding was biologically
11 significant. And biologically
12 significant would typically be linked
13 to a finding that has statistical
14 significance in an epi study unless
15 the study was not designed to be able
16 to answer the question properly.

17 So -- and I've discussed that a
18 little bit yesterday with Mr. Smith on
19 the issue of power to detect. So
20 that's something you do consider in
21 epi.

22 But, yes, statistical
23 significance certainly goes into your
24 weight of the evidence there.

25

1 QUESTIONS BY MS. BRANSCOME:

2 Q. Okay. You talked about you're
3 intending to offer an opinion with respect to
4 what a company is required to do under the
5 regulations; is that correct?

6 A. Yes.

7 Q. Okay. What regulations are you
8 specifically referring to?

9 A. So cosmetic regulations that
10 exist within -- so it's the entire process as
11 I describe how cosmetic -- what -- are
12 cosmetics subject to regulation by FDA? Yes.
13 What are the types of things that companies
14 have to do before they're marketed, what does
15 the company have to do once the product is on
16 the market, those kinds of things.

17 Q. Have you ever worked directly
18 for any regulatory agency?

19 A. No, I have not.

20 Q. And suffice it to say you have
21 never been in a decision-making position
22 within a regulatory agency, correct?

23 A. That's correct, I have not.

24 Q. Have you ever been in a
25 decision-making position with respect to a

1 company evaluating compliance with FDA
2 regulations with respect to cosmetics?

3 A. Yes.

4 Q. Okay. What is your experience
5 with respect to that?

6 A. So that's -- one of the clients
7 that I currently work for where I am asked to
8 provide input on advertising, promotion and
9 labeling of some of the products and then
10 also some of the ingredients that are being
11 promoted for use to -- to produce cosmetic
12 products. So it's the idea of providing that
13 advice over my understanding of the
14 regulations what can be said and can't be
15 said about certain ingredients.

16 This company is involved in
17 making both ingredients but also some
18 finished products now based on -- it's a
19 large company that owns a lot of little
20 subsidiaries.

21 Q. My question, though,
22 Dr. Plunkett, was, have you ever been in a
23 decision-making position for a company
24 evaluating compliance with FDA regulations
25 with respect to cosmetics?

1 MS. PARFITT: Objection. Asked
2 and answered.

3 THE WITNESS: So that's what
4 I'm saying. They're relying on my
5 input to make a decision on what will
6 go in the materials.

7 QUESTIONS BY MS. BRANSCOME:

8 Q. Do you have decision-making
9 authority within that company or, as you
10 described it, are you providing advice and
11 input?

12 A. I'm providing advice, but the
13 things I'm advising on are the things that
14 happened. So in other words, they don't have
15 anybody in the company that understands the
16 process of what they can say. So I -- I
17 advise them that you need to remove this
18 language or that this is more appropriate
19 language. They make those changes, and then
20 that is what is done.

21 So I agree, I'm not an employee
22 of that company. I am a consultant working
23 with the company, but it is a little
24 different than some of the work that I do
25 where I -- what I -- the advice that I'm

1 giving is actually something that I know
2 actually happened. Sometimes you give advice
3 to companies, but it doesn't -- we have no
4 idea whether the company actually follows our
5 advice.

6 Q. My question is slightly
7 different, Dr. Plunkett.

8 If you were to give advice to
9 the company that you've referenced as having
10 experience with cosmetic regulation
11 compliance that that company chose not to
12 follow, that company has the ability to
13 ignore your advice, correct?

14 A. Yes, I would imagine that they
15 could do that.

16 Q. Okay. Have you ever drafted
17 regulations that relate to cosmetics?

18 A. Actually drafted a regulation?
19 No, I have not.

20 Q. All right. You reference in
21 your report language out of 21 CFR 740.1, and
22 specifically -- you reference it in a few
23 places. And I can direct you specifically to
24 paragraph 22 in Exhibit 4.

25 A. Yes. I'm there.

1 Q. All right. And do you see here
2 you have replicated language from 21 CFR
3 740.1 that reads, "The label of a cosmetic
4 product shall bear a warning statement
5 whenever necessary or appropriate to prevent
6 a health hazard that may be associated with
7 the product"?

8 Do you see that?

9 A. Yes.

10 Q. And you added emphasis on
11 particular portions of this sentence,
12 correct?

13 A. Yes, I did that, exactly.

14 Q. All right. Now there's a
15 clause in this sentence that states,
16 "Whenever necessary or appropriate."

17 Do you see that?

18 A. Yes.

19 Q. You did not emphasize that
20 language; is that correct?

21 A. That's correct, I did not.

22 Q. What is your understanding
23 as -- what you describe as an FDA regulatory
24 specialist of the meaning of "whenever
25 necessary or appropriate" in 21 CFR 740.1?

1 A. So it's -- first off, you would
2 use the common English language definition.
3 I don't believe that those -- I haven't seen
4 a definition separate within the regulations.
5 Sometimes there will be.

6 So based on that and my
7 experience and the looking into what others
8 have described about this, this is the idea
9 of considering how the product is used, is
10 one of the -- one of the concerns that you
11 have, and whether or not the -- based on how
12 the product is used and how the product is
13 being sold, that in order to prevent a health
14 hazard, a warning hazard -- a warning
15 statement would be needed.

16 Q. Can you cite to me any language
17 within the regulation or even supporting
18 documentation, a comment, something of that
19 nature, that would define "whenever necessary
20 or appropriate" with respect to how the
21 product is used?

22 MS. PARFITT: Objection.

23 THE WITNESS: I don't think I
24 understand your question.

25 Are you asking me to cite to a

1 reference or a part of the regulation
2 where they explain it, or what are you
3 asking me? Guidance document or --

4 QUESTIONS BY MS. BRANSCOME:

5 Q. Yes. Can you point me to
6 anything other than your personal view of the
7 interpretation of this language that would
8 tie the requirement "whenever necessary or
9 appropriate" to how a product is used?

10 MS. PARFITT: Objection. Form.

11 THE WITNESS: I'll have to go
12 look for you whether there's a
13 guidance that states it that way.
14 This is based on my experience in
15 dealing with the products in the past.

16 I think that's also consistent
17 with what is described, I would say to
18 you, within -- it's consistent -- what
19 I'm describing to you, it's consistent
20 as well with how the CIR standard for
21 safety assessment is done, looking at
22 the issue of the -- of the -- of the
23 use.

24 QUESTIONS BY MS. BRANSCOME:

25 Q. When you say that you're basing

1 your interpretation of the clause "whenever
2 necessary or appropriate" on your personal
3 experience, can you point me to something
4 specific?

5 MS. PARFITT: Objection.

6 THE WITNESS: Are you asking
7 me -- are you asking me if I've ever
8 had a company that I worked for that
9 that particular clause in here was
10 extremely important to how we
11 interpreted it? I don't think I can
12 point you to that. I don't recall
13 ever having to do that specifically.

14 Or is it something different
15 you're asking me?

16 QUESTIONS BY MS. BRANSCOME:

17 Q. Dr. Plunkett, I asked you what
18 your basis was for interpreting the language
19 "whenever necessary or appropriate" means
20 that it's related to how a product is being
21 used, and the answer that you provided was
22 that it was based off of your personal
23 experience.

24 So I'm asking you, what is that
25 personal experience that gives you the basis

1 for that specific interpretation?

2 MR. MEADOWS: Objection.

3 MS. PARFITT: Objection.

4 THE WITNESS: So it's in my
5 experience in dealing with companies
6 that make products and what types of
7 warnings are put or not put onto -- or
8 not -- or on labeling. So I don't
9 know how else to answer it other than
10 that.

11 I can go back and look at the
12 guidance documents to see if that is
13 described in another way, but I don't
14 recall that.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. So as you sit here today,
17 you're not able to provide me either with a
18 third-party document or an independent
19 document interpreting "whenever necessary or
20 appropriate" as you've suggested today, nor
21 can you give me specific example from your
22 personal experience; is that correct?

23 MS. PARFITT: Objection.

24 THE WITNESS: Well, I
25 certainly -- I'd have to go back and

1 look at my documents in order -- the
2 first part of your question, I'd have
3 to go back and look. Off the top of
4 my head, I can't tell what I would
5 point you to.

6 On the second one, I think I
7 was telling you, is I don't -- I've
8 never -- I don't have a client that
9 I've worked for where that part of the
10 language was the only issue that I had
11 to deal with when I'm looking at
12 whether or not the product needs a
13 warning or not.

14 So typically -- I'm just
15 telling you that when I have looked at
16 labeling for products and looked at
17 the issue of does it need a warning
18 statement, when I'm reading it as
19 "whenever necessary or appropriate,"
20 I'm looking at whether or not the
21 ingredient that I'm concerned about
22 within the product, how that is used
23 or what the exposure pattern would be,
24 route of exposure, how those things
25 might relate to how I would assess the

1 safety issue at hand. And so that's
2 what I'm trying to tell you.

3 QUESTIONS BY MS. BRANSCOME:

4 Q. Okay. You also have --
5 changing topics a little bit, in this -- in
6 your report marked as Exhibit 4, if you could
7 turn to paragraph 10.

8 On page 7, you state on the
9 first paragraph on page 7, "In other
10 instances I have directed others to perform
11 searches on my behalf," and this is with
12 respect to identifying documents for review
13 in forming your opinions.

14 What did you mean by that?

15 A. So in addition to doing my own
16 searches of the database, sometimes I -- I
17 have called the attorney's office and asked
18 them to -- to do a search for certain things
19 that I'm looking for to add to. So in other
20 words, I have a document I've identified.
21 I'm looking for other documents like that in
22 the large millions and millions of documents
23 that are available. And so sometimes I will
24 ask attorneys to do -- to look in the
25 database for other documents like the ones

1 that I've identified.

2 Q. And without getting into
3 anything that would be -- that would call for
4 information protected by the attorney/client
5 privilege or attorney work product, what
6 percentage of the overall searches for
7 relevant documents from these particular
8 databases that are discussed in paragraph 10
9 would you say that you have done yourself as
10 opposed to directed others to do?

11 A. Well, initially when I first
12 started searching, those were my own searches
13 exclusively. I would say that more recently,
14 in the last year, since I haven't added any
15 real new areas but there's new documents that
16 have become available, so anything -- any of
17 the searches probably in the last year that
18 dealt with new discovery that was produced, I
19 would have asked the attorneys to do some of
20 the searching in that for me. Like I'm
21 looking for documents that are similar to
22 this document that I cited in my original
23 report around this same frame that may be
24 discussing this same topic area.

25 So in the last year I have

1 asked them to do that more than I have done
2 it, but initially it was what I did
3 initially.

4 Q. Okay. Do you keep any records
5 of the various document searches either that
6 you have performed or you have asked to be
7 performed?

8 A. No, I don't. My record would
9 be -- the initial -- the record would have
10 been what I listed in my reliance list for
11 you in the initial report, but since then it
12 would just be what is going to be changing
13 within my reliance list, looking at
14 additional documents. That's the only way I
15 could identify for you. That would be my --
16 my trail to know what was new and what was
17 not.

18 Q. My question is slightly
19 different. Understanding that you have
20 provided to some extent a record of the
21 documents, my question is: Do you have any
22 type of record for the nature of the
23 searches, what it was that you set out to
24 identify in the database and how did you go
25 about finding those documents?

1 A. So that might cross over into
2 work product because it's not my database,
3 but I don't know how to answer that. I mean,
4 I'm sure -- it's very possible that in the
5 database you can track that, but I -- I don't
6 know.

7 MR. MEADOWS: Okay.

8 THE WITNESS: I don't have
9 anything saved on my computer that
10 way, but when you go to the database
11 itself, it's possible you could track
12 that. I just don't have a record on
13 my computer in my office.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. When you made the decision at
16 some point in time -- it may have been even
17 prior to you issuing your first report --
18 that you wanted to look at company documents,
19 did you set out specific categories of
20 documents that you wanted to review?

21 A. Not so much categories but key
22 words. So -- and areas. I guess areas is
23 what I -- yes, I was focusing, for example,
24 in my initial report on documents that
25 described what was known -- what the company

1 was discussing about cancer, ovarian cancer,
2 cancer generally. So that was a key word
3 used.

4 And then I also was linking
5 that in different searches with different
6 time periods such as the NTP review process
7 and dates. You can, you know, narrow down by
8 dates or by the CIR process. Those kinds of
9 things.

10 So I did start with that,
11 trying to understand what -- what is -- what
12 was in the company files or in the files I
13 had access to, the database, that dealt with
14 those kinds of things because those aren't
15 things that I could get to publicly.
16 Obviously in the literature. So I had to --
17 if I wanted to understand what the company
18 knew, I had to go into their database to find
19 out, you know, what they knew -- what they
20 knew or were discussing over time about the
21 ovarian cancer issue or about asbestos in
22 talc or about CIR process, things like that.

23 Q. Using the reports that you have
24 produced, Exhibits 2, 3 and 4, really, and
25 the full -- the entirety of the materials

1 that you have produced in the MDL, is there
2 any way that someone reviewing those
3 documents, and those documents alone, could
4 replicate the searches that you have
5 conducted in the company databases?

6 MR. MEADOWS: Objection.

7 THE WITNESS: I don't know.

8 That's a good question. I've never
9 thought about whether you could
10 replicate or not.

11 I mean, I think I've told you
12 what I did. My strategy was to focus
13 on topic areas. So I think you
14 might -- by topic areas, if you use
15 the same kinds of topics areas as
16 described, I think you would come up
17 with documents that -- what it focused
18 down to.

19 For example, I also would
20 sometimes, as linking those words, I
21 might put in J&J documents only or
22 Imerys documents only, because the
23 database has a variety -- and the
24 PCPC. There's some different ways by
25 the Bates numbers that you can

1 segregate documents as well. But I
2 don't know other than that. That's
3 all I can tell you.

4 QUESTIONS BY MS. BRANSCOME:

5 Q. You would agree with me that
6 your report does not contain a complete
7 explanation of the process by which you
8 identify company documents to review,
9 correct?

10 A. I haven't laid out my search
11 structure, that is true.

12 Q. All right. Now, the articles
13 that you have listed on your reliance list,
14 have you read each and every one of those
15 articles?

16 A. Unfortunately, yes, over time I
17 have. Some of them I have only read parts of
18 them. For example, if I started reading a
19 document and I felt that it was something I
20 pulled that really wasn't directly on point
21 for an area I'm covering, I may not have read
22 every word, but certainly I have been through
23 each of those, yes.

24 Q. Are there any articles in your
25 reliance list, that you maintained on your

1 reliance list, that you read, but then once
2 you started reading decided weren't relevant
3 to the opinions that you were offering?

4 A. I would have to look to answer
5 that for you. I don't know. If you want me
6 to do that, I'd have to look.

7 Q. I ask you more as a process
8 matter.

9 A. Oh.

10 Q. If you pull an article and you
11 start reading it and you realize that it is
12 not relevant to the opinions that you offered
13 in this case, the example that you just gave,
14 is it something that you would include in
15 your reliance list?

16 A. Yes, I -- I have given you
17 everything I retrieved. So if I retrieved
18 it, you would have, yes, absolutely.

19 Q. Okay. So it's fair to say of
20 the articles that are on your reliance list,
21 you could not say as you sit here today that
22 you have read each and every word of each and
23 every one of them, correct?

24 A. That's correct. And I could
25 probably tell you -- I could give you a

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1 little guidance in that possibly if I went to
2 my list, I could try to pull some out that I
3 recognize, but that's all I would be able to
4 do for you.

5 Q. Okay. How did you go about
6 identifying what articles you wanted to
7 review in forming your opinions in the MDL?

8 A. So first off, I went back to
9 what I already had. So my MDL report is a --
10 is a compilation of a lot of material that's
11 in my first few reports. That was the basis
12 for some of the things that went into it.

13 So I didn't -- I did do,
14 though, a updating on literature searches for
15 the MDL report, looking for anything new, for
16 example, in the area, especially the area of
17 cancer data or reports of dealing with
18 ovarian cancer either -- or any articles
19 dealing with the link between inflammation
20 and cancer, ovarian cancer, generally.
21 That's one of the areas I updated looking at.

22 And then I did -- I don't think
23 I did any large, new searches, however,
24 because honestly the areas covered here are a
25 little narrower than what was covered here.

1 I don't believe that there was any from the
2 published -- the publicly available medical
3 literature. There wasn't a need to do a
4 whole new area of search. It was more
5 updating the things that I've done in the
6 past.

7 So it's a real easy search to
8 update because you can just put in talc and
9 cancer and just look at -- get lots, but you
10 can then just start chronologically and look
11 what was published in the last year, for
12 example.

13 Q. Okay. Earlier when we were
14 discussing the fact that you in some
15 instances have asked your husband to pull
16 articles, have you maintained any records of
17 the searches that you have done with respect
18 to scientific literature, including the
19 searches that you have asked your husband to
20 do?

21 A. I have not. It's possible that
22 there are records on billing from the library
23 that tells you how many I ordered at
24 different times, but that is the only
25 records, because we do have to pay the

1 library for the retrieval.

2 Q. Okay. And if I understood what
3 you said earlier correctly, you indicated
4 that any article you have ever pulled for
5 review, you have listed on your reliance
6 list; is that correct?

7 A. Yes. And when I -- and let's
8 just make sure we're talking about the same
9 thing.

10 So, you know, in my reports I
11 typically have articles cited in the report
12 separate from the reliance list. So I'm
13 talking about the reliance list, right?
14 Okay.

15 So -- because I do -- I do
16 usually -- I don't know whether I did that in
17 this report, but I typically have a list of
18 articles cited at the back called references,
19 that is, things that you're actually seeing
20 in the report body, and then there should be
21 a separate reliance list sent to you as an
22 appendix. I don't know what the appendix
23 was.

24 Q. Well, so then let's clarify
25 that. So, Dr. Plunkett, when you're

1 referring to the reliance list, are you
2 referring to the list of articles that begins
3 on page 40 of Exhibit 4, or is there a
4 separate document?

5 A. There's a separate document.
6 So it -- that's -- I usually call reliance
7 list the separate document. I call this
8 references cited. So I apologize for that
9 confusion.

10 So these, I have read every
11 word. If it's in my reference list, those
12 are not an issue of not having read every
13 word, and these should all be cited somewhere
14 in the report.

15 Q. Okay. If you could turn to
16 paragraph 21 in your initial report.

17 A. Yes, I'm there.

18 Q. Okay. So we're looking at
19 paragraph 21 in Exhibit 2. This is on
20 page 10.

21 Do you see there is a sentence
22 here that refers to -- it's referring
23 generally to the topic of the ability of talc
24 to migrate from the site of application to
25 the ovaries.

1 Do you see that?

2 A. Yes.

3 Q. And then the next sentence
4 states, "This issue was discussed by
5 scientific and regulatory bodies that review
6 the toxicokinetics of talc."

7 Do you see that?

8 A. Yes.

9 Q. And in parentheses it
10 identified EPA 1992, IARC 2010, and CIR 2013.

11 Do you see that?

12 A. Yes.

13 Q. Okay. And then if you could
14 turn to Exhibit 4, which is your MDL report,
15 at paragraph 43. It's on page 28.

16 Are you with me?

17 A. Yes, I am.

18 Q. You see that the exact same
19 sentence appears -- well, not the exact same.
20 It's been slightly modified to combine the
21 first two sentences. But here you cite only
22 to EPA 1992 and IARC 2010.

23 Why did you remove CIR 2013?

24 A. Because of my further
25 evaluation since my initial report in 2016 of

1 the process that was involved in the drafting
2 of the CIR and the actual production of the
3 report.

4 Q. Is it your position that the
5 migration of talc was not evaluated as part
6 of CIR 2013?

7 A. No. That's not my position,
8 no.

9 Q. Okay. And so would the
10 sentence that's contained in paragraph 43 in
11 Exhibit 4, which is your MDL report, if you
12 cited to CIR 2013 in the parenthetical there,
13 would that not be an accurate citation?

14 A. I believe it would not be an
15 accurate citation because I have formed
16 opinions about the reliability of that
17 document at this point in time.

18 So it has to do with -- I'm
19 citing to authorities here that I believe are
20 reliable as far as the discussion that I see,
21 and it's a different -- I have a different
22 opinion now about the CIR report, which I lay
23 out in pretty detail, I think.

24 In fact, if you go to my
25 section following this now in -- you'll

1 understand one of the issues I had was the --
2 the difference in the evidence that was
3 actually available once you dig into it a
4 little further versus what they actually
5 reviewed. That's one of the issues.

6 Q. And I'll follow up with some
7 more questions about the CIR, but my question
8 here is, the sentence in your report simply
9 states, "The migration of talc internally
10 after perineal application was discussed by
11 scientific and regulatory bodies that review
12 the toxicokinetics of talc."

13 Would it be inaccurate to say
14 that as part of the CIR 2013 process that
15 body did, in fact, discuss the migration of
16 talc internally after perineal application?

17 A. It is true that they did
18 discuss it. I just have an issue with the
19 reliability of their findings.

20 Q. And so you made the decision to
21 just remove it from the citation; is that
22 correct?

23 A. Yes, at this point -- at this
24 point, at this report, that's exactly right.

25 Q. All right. And then I had

1 another question. In paragraph 43, you added
2 two studies from your prior -- that were --
3 that did not appear in your prior report, and
4 it was Gardner 1981 and Edelstam 1997. This
5 related to animal studies showing that in
6 some species talc can migrate from the lower
7 to the upper genital tract?

8 A. Yes.

9 Q. Okay. Were those studies that
10 you were aware of before drafting your prior
11 reports?

12 A. I don't know that they -- I
13 can't answer that without looking at my
14 reliance materials for the original report.
15 I did identify additional articles, and
16 there's also additional articles cited here
17 in earlier paragraph 43 that were not cited
18 in my original report as well. I don't think
19 I had the -- the Kunz article then cited.
20 I'd have to go back and look.

21 So it's possible that they were
22 in my -- when I say my reliance materials, my
23 original report also had a larger list of
24 literature I didn't cite. So I'd have to
25 look. I can't tell you whether I had them or

1 I did not.

2 Q. Okay. With respect to Edelstam
3 1997 study, do you happen to know the title
4 of that article? Even an approximation would
5 work.

6 A. It'll be -- should be back
7 here. Just a second. If it's not here,
8 that's a mistake.

9 Oh, here it is. "Retrograde
10 migration of starch in the genital tract of
11 rabbits."

12 Q. So you are citing that article
13 for the proposition that animal studies have
14 demonstrated that talc can migrate from the
15 lower to upper genital tract?

16 A. Yes, I'm citing it because it's
17 relevant to the issue of particle migration,
18 which talc is a particle. So, yes, that's
19 correct.

20 Q. Okay. But that study did not
21 specifically deal with talc migration,
22 correct?

23 A. No. Well, it -- it's relevant
24 to talc migration, but you're exactly right,
25 they looked at the starch migration, yes. Or

1 particles that were starch, yes.

2 Q. We'll cover this in more
3 detail, but is it your opinion that all
4 particles have similar characteristics with
5 respect to their ability to migrate in the
6 genital tract?

7 A. It's my -- I don't know if I'd
8 state it quite that way. What I would say is
9 that the evidence shows that particles
10 generally have the ability to move up the
11 reproductive tract in women, yes, and that if
12 a particle is one that is similar to talc or
13 some of the other ones where the information
14 has been collected, I would characterize that
15 as being within that, quote/unquote,
16 relevance of particles.

17 That doesn't mean all
18 particles, but certainly in the ones that I
19 have looked at and the data I've relied upon,
20 there's a variety of different types of
21 particles or substances that have been
22 studied and shown to be able to migrate.

23 Q. So let's take Edelstam 1997 as
24 an example.

25 Did you do any analysis that

1 you can point me to that establishes that
2 starch would have a similar migration pattern
3 as talc?

4 A. So I would say that the paper
5 itself shows -- talks about the movement of
6 starch, but are you asking something
7 different?

8 Are you asking me have I done a
9 specific analysis of any differences that may
10 occur between the migration pattern of starch
11 and talc? Is that what you're asking me?

12 Q. That is what I'm asking you.

13 A. I certainly didn't do an
14 in-depth analysis of the differences, no, but
15 based upon my review of the literature, I
16 believe that that paper is relevant to the
17 overall question of migration of particulate
18 through the reproductive tract, including
19 particles of talc.

20 Q. Regardless of whether or not it
21 was an in-depth analysis, can you point me to
22 anything other than just your belief after
23 having read these articles that starch and
24 talc would have similar migratory
25 characteristics in the human or animal

1 genital tract?

2 MS. PARFITT: Objection.

3 THE WITNESS: Again, I haven't
4 done an in-depth analysis. I mean, as
5 a toxicologist, there are differences
6 between starch and talc, absolutely.
7 For example, starch would -- I would
8 expect to be more easily solubilized
9 within fluids, and so that could
10 affect the ability of them to actually
11 not migrate as well as a talc
12 particle, which would be less soluble
13 than the starch would be.

14 And there's -- I even --
15 there's a paper I have in here, and I
16 can look for it if you want, that
17 talks about that difference, and it's
18 one of the issues of cornstarch versus
19 talc, on whether or not you would
20 expect to get the long-term chronic
21 responses with the difference between
22 those two substances.

23 So I do think there's
24 difference, absolutely, as
25 toxicologists generally. And the only

1 reason I'm citing this paper is
2 because I'm trying to be complete
3 about people that have looked at this
4 issue. And certainly it was a study
5 that looked at this issue and talks
6 about the movement.

7 But I wouldn't expect starch
8 and the talc to have the same
9 liabilities, and I also wouldn't
10 expect them to move exactly the same
11 speed maybe. That's very true.

12 QUESTIONS BY MS. BRANSCOME:

13 Q. So you would agree with me that
14 Edelstam is not a study demonstrating that
15 talc can migrate from the lower to upper
16 genital tract, correct?

17 MS. PARFITT: Objection. Form.

18 THE WITNESS: I wouldn't say it
19 that way. What I would say instead is
20 that Edelstam is a study that forms
21 the overall weight of the evidence for
22 the ethics -- for the studies that are
23 available that address the issue of
24 migration, but certainly it is not
25 studying talc. So I don't disagree

1 with you there.

2 Unfortunately, the majority of
3 the information that I have relied
4 upon, and others such as the FDA in
5 making their statements about
6 migration, is not all directed studies
7 just to talc. It's looking at the
8 issue of particle movement.

9 QUESTIONS BY MS. BRANSCOME:

10 Q. Now, in terms of doing your
11 risk assessment -- well, let me get back. We
12 covered this earlier, and I want to return to
13 it for a moment. Just to confirm: For your
14 work in the MDL, you did not do a Bradford
15 Hill analysis, correct?

16 A. I did not sit down and do a
17 Bradford Hill analysis when I started writing
18 this report. I have done a Bradford Hill
19 analysis in the past, which is in my original
20 reports, but I certainly did not redo a
21 Bradford Hill when I sat down to draft my MDL
22 report, that is true.

23 Q. Okay. Let me be more precise.
24 In the report that you have
25 produced that contains a description of your

1 opinions in the MDL, you have not set forth a
2 Bradford Hill analysis in that document which
3 is identified as Exhibit 4, correct?

4 A. That is true, yes.

5 MS. PARFITT: Objection.

6 QUESTIONS BY MS. BRANSCOME:

7 Q. And in fact, the paragraph that
8 you -- or paragraphs that you have in your
9 prior reports that reference a Bradford Hill
10 analysis, those have not -- those have
11 actually not been replicated in any form in
12 Exhibit 4, correct?

13 A. Yes, because, again, it was not
14 my role to do general cause.

15 Q. Okay. So then when we look at
16 the methodology that you employed in reaching
17 your opinions that are contained here in
18 Exhibit 4, how would you characterize the
19 methodology?

20 A. As I have in the report. I
21 talk about it being a risk assessment or a
22 safety assessment, that you could use those
23 terms interchangeably here. And then I've
24 also used a weight of the evidence as a tool
25 to go through the different steps of the risk

1 assessment.

2 Q. Okay. What publication would
3 you direct me to that has used the same
4 methodology that you have used to reach your
5 opinions in Exhibit 4?

6 A. I think I cite you to -- cite
7 you to some of those. You could -- well, the
8 directly relevant one would be looking at the
9 chapter on risk -- toxicology in the
10 reference manual on scientific evidence.

11 You can also go to the NRC
12 report where they -- it lays out the
13 different steps that you use when you kind of
14 break data apart into exposure versus
15 response information.

16 And then I cite to -- there are
17 some guidance documents that I cite to, and
18 this is in paragraph 13. And I'd have to
19 pull them out again to tell you which ones
20 relate to different pieces because some of
21 these are -- some of these documents are
22 specific to only, for example, maybe one part
23 of what I did.

24 But certainly the risk
25 assessment process at IARC is -- they do what

1 I call a hazard assessment. They identify
2 hazard and they couldn't quantify risk, but
3 the steps they go through are essentially the
4 same types of steps that I went through as
5 far as gathering data on not just response
6 but also the potential for exposure and how
7 that relates to the response.

8 And then also the data that
9 I've collected on the biologic effects of
10 talc, toxicology of talc, are also discussed
11 within that document as well.

12 Q. Okay. Focusing specifically on
13 the weight of the evidence tool, as you
14 describe it, is there a particular document
15 or publication that I would go to that could
16 lay out the same process that you used for
17 how you weighted certain pieces of evidence?

18 A. So the documents that I've
19 cited for you in paragraph 13 talk about what
20 weight of the evidence is generally, but if
21 you read what it is, it's essentially a
22 process that each scientist brings their
23 experience, training and judgment to.

24 So I try to lay out for you in
25 my discussion of the literature my thought

1 process as I review each piece of
2 information, and that is what you do as part
3 of weight of the evidence. You gather all of
4 the relevant information that you can find
5 that address the question you're trying to
6 answer, and since I'm looking at both
7 exposure and response, I gather different
8 pools of information.

9 Q. You would agree that there are
10 ways to do a weight of the evidence
11 assessment of published literature that
12 assign, for example, quantitative values to
13 particular pieces of evidence, correct?

14 A. Certain individuals have put
15 together, but there's no one general accepted
16 process that everyone uses. So I -- that's
17 the issue. Again, there are certain --
18 certain cases where I've seen that done, and
19 then there are many -- most cases that it's
20 not what's done.

21 Q. Okay.

22 A. Another body, by the way, that
23 I -- it's new. It's not in paragraph 13. I
24 just want to make sure I tell you that so
25 we're clear. If you look at the Canadian

1 document, they also -- in fact, a lot of what
2 they have, you'll see the same literature
3 described within my assessment as well.

4 Q. So using the Canadian
5 assessment as an example, for instance, in
6 that assessment there were actually values
7 assigned to particular pieces of literature,
8 correct?

9 A. Mainly the epidemiological
10 literature, that is true. Again, but I'm not
11 doing causation, so I didn't approach it that
12 way.

13 But certainly if you look at
14 what I did, it's consistent with that because
15 I talk about the differences between the
16 limitations of a case-control versus a
17 prospective study. I talk about both the
18 positives and the negatives within the
19 database, but I don't lay it out in a table
20 like they do. But it's certainly the same
21 basic process.

22 I was actually quite surprised
23 at how similar the database of information
24 that they reviewed was to what I honed in on
25 as well.

1 Q. Okay. As you were forming your
2 opinions, Dr. Plunkett, about whether or not
3 there is a risk associated with the use of
4 Johnson's baby powder with respect to ovarian
5 cancer, how do you keep track of the pieces
6 of scientific evidence that you have reviewed
7 and the respective weight that you give to
8 them?

9 Presumably you did not read
10 everything in one day, for example?

11 A. No. That's correct. So I
12 typically will -- I typically will save the
13 papers -- when I read the papers, I will
14 often highlight in yellow information that I
15 think is going to -- will be extremely
16 relevant. I don't put notes on the document.
17 I highlight in yellow on the PDF file to use
18 that to write.

19 And I also start drafting
20 report very early, which then gets
21 overwritten and actually ends up looking like
22 an outline that eventually becomes the
23 report.

24 So one of the ways I keep track
25 of things is I may put a paragraph name that

1 I know I'm going to write, such as exposure
2 migration, and then I -- as I'm reading a
3 paper, I'll type in a paper -- the ones that
4 I believe are important to my overall
5 assessment. So I will do that as I'm -- as
6 I'm going through the evidence.

7 So that's one of the tools I
8 use, but I don't keep notes. I just kind of
9 use that as a living document that eventually
10 becomes a report.

11 Q. Do your opinions ever change as
12 you read additional pieces of scientific
13 evidence?

14 A. Yes, it does. It may change.
15 And it often -- often the changes, though,
16 are not that I believe -- with the exception
17 of epidemiology. In other areas.
18 Epidemiology is a little bit different issue
19 when you're reviewing studies.

20 But on toxicology I always
21 start with reviews and regulatory
22 authorities, looking at what others have said
23 generally about the toxicology. And so even
24 though I may refine opinions differently or I
25 might change, I certainly wouldn't agree to

1 work on a project to start with if my initial
2 reviews on hazard, for example, didn't
3 convince me that I believe that there is a
4 hazard. But you refine it from there.
5 That's exactly right.

6 So there are cases, however,
7 where I'm asked to work on a project where
8 there is no review or regulatory authority or
9 any kind of assessment over a period of
10 years, and in those cases there are times
11 when I start working on a project and I stop
12 and say, "I can't do this." Because that
13 happens, yes.

14 So opinions do change sometimes
15 based on review of additional information.

16 Q. Is there any documentation that
17 you've produced either in your report or
18 otherwise in the MDL that would allow someone
19 reviewing the material to understand the
20 order in which you reviewed materials or the
21 specific weight that you assign them?

22 A. So order of review, no. I
23 don't think you would know that other than --
24 you will note order of review if you look at
25 the differences in the literature cited in my

1 original report versus in the MDL.

2 So in my original reliance
3 list, if there were documents that weren't
4 there and they're now here, obviously that
5 tells you it was a review.

6 On the issue of a -- of the
7 weight of the evidence process, the only
8 answer I can give you for that is that
9 articles that I believe are -- are reliable,
10 are relevant and are -- those are kind of
11 the -- you look at the reliability of the
12 studies, whether they're peer-reviewed or not
13 or if they have proper controls put into
14 place, things like that, whether or not
15 the -- they're relevant to the question at
16 hand. That you can get from looking at how I
17 discuss them in the document. But certainly
18 there's no, like, summary of that.

19 But certainly -- I think you
20 understand -- you should understand when you
21 read my report what weight I'm giving based
22 on how I'm describing those -- those
23 materials. I mean, it's --

24 Q. Well, for example, you do have
25 different studies that you've identified in

1 your report that have been criticized by
2 others at some point in time, correct?

3 A. Yes, that's true.

4 Q. Okay. Now, in some instances
5 you state that you then give little weight to
6 those studies, correct?

7 A. Yes.

8 Q. But in other instances you find
9 the criticized study to be helpful and
10 informative, correct?

11 A. That's true. Because, again,
12 judgment -- as anybody does weight of the
13 evidence, different scientists can have
14 different judgment.

15 Mainly, I think, when I look at
16 the differences in that -- in that regard, I
17 think you should pay attention to what the
18 person is. So as a toxicologist, I may view
19 a certain type of -- piece of data very
20 differently than an epidemiologist may view
21 it, as far as the reliability or the
22 relevance, because we're coming at it from a
23 different training and experience and
24 judgment -- set of judgment on what is
25 important to a toxicologist when I'm talking

1 about risk versus how an epidemiologist might
2 talk about risk.

3 Q. Could two different
4 toxicologists review the same piece of
5 literature and give it very different weight?

6 A. I don't know about different
7 weight, but they certainly -- I know people
8 come to different conclusions based on their
9 overall assessments. That happens,
10 definitely. I mean, there are always going
11 to be individuals that look at things
12 differently.

13 I know in this case there are
14 people -- I've seen defense experts that
15 reports in -- not in the MDL but in other
16 cases, where people disagree with some of my
17 opinions, and I disagree with their opinions.
18 That happens.

19 Q. Okay. And so if I were --
20 well, let me just ask something. You have
21 not provided any sort of quantitative
22 assessment of the weight that you gave
23 different pieces of evidence that you cite in
24 forming your opinions in the MDL, correct?

25 MS. PARFITT: Objection.

1 Misstates her testimony.

2 MR. MEADOWS: Objection.

3 THE WITNESS: So I don't report
4 for you a table where I quantify that,
5 that is correct, but certainly that
6 is -- because, again, based upon
7 looking at the way that I was trained
8 and the documents that I'm talking --
9 I'm pointing you to to describe how to
10 do weight of the evidence, it is
11 not -- it is not a numerical exercise,
12 how many here, how many there, this
13 one gets 5 points because of this or
14 6 points because of this.

15 It's more an issue, again, of
16 judgment. It's the idea of looking
17 across all of the available
18 information and determining whether or
19 not, based on that, it's your opinion
20 that there -- that, for example,
21 talc -- talc's toxicity profile
22 includes cancer. That's one of the
23 judgments -- weight of the evidence
24 judgments you make, for example.

25

1 QUESTIONS BY MS. BRANSCOME:

2 Q. So -- but, Dr. Plunkett, just
3 to be clear, you do not provide a numerical
4 value to the particular pieces of evidence
5 that you have considered as part of your
6 weight of the evidence assessment in the MDL,
7 correct?

8 MS. PARFITT: Objection. Form.

9 THE WITNESS: So I do not
10 provide a numerical value as you see
11 it laid out, for example, in the
12 Canadian table, but certainly I do
13 judge articles that I include in my
14 weight of the evidence based on a
15 system that includes different
16 considerations such as -- like I said,
17 peer-reviewed or not, that makes an
18 issue.

19 Whether or not the study that's
20 being reported is the only one -- the
21 first or is this something that is --
22 that is describing an assessment
23 that's been done by someone else and
24 so you see a repetition or a
25 consistency among the studies that

1 you're looking at.

2 The robustness of the data.

3 For example, the NTP GLP quality
4 animal study, very high quality in the
5 weight of the evidence. And I talked
6 to you about that. In fact, it --
7 even though people criticize that
8 study, that study is very valuable for
9 looking at biologic changes that are
10 consistent with a carcinogenic
11 mechanism being initiated.

12 So even though you may say that
13 you can't quantify risk from that
14 animal study as far as calculating a
15 cancer potency factor, what you can do
16 is use that study of high quality to
17 make judgments within a weight of the
18 evidence for risk.

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Dr. Plunkett, you understand I
21 have seven hours today, and I -- while I'm
22 very interested in the answers that you give,
23 if we could just -- we will get to things
24 like NTP when we get there, if you could just
25 attempt to answer the question that I've

1 asked.

2 I simply asked the question:
3 Are there numerical values assigned to the
4 particular pieces of evidence that you have
5 considered as part of your weight of the
6 evidence assessment in reaching your opinions
7 in the MDL; yes or no?

8 A. And I said to you, not in the
9 way that it's done -- I assume you're
10 referring to something like what was done --
11 what's in the Canadian epidemiology table. I
12 have not done that, no.

13 Q. Okay.

14 A. That's exactly right.

15 Q. Have you provided a qualitative
16 chart, for example, of the evidence that you
17 have considered in forming your opinions in
18 the MDL?

19 MS. PARFITT: Objection. Form.

20 THE WITNESS: I don't know what
21 you mean by qualitative chart. I
22 certainly have -- I certainly, I
23 believe, have given you qualitative
24 descriptions of my weight within my
25 discussions of each study, yes, I have

1 done that.

2 QUESTIONS BY MS. BRANSCOME:

3 Q. You mention in response to the
4 prior question that you have a system for
5 weighting the pieces of evidence that you
6 have reviewed.

7 Can you point me to paragraphs
8 in your report marked Exhibit 4 that would
9 outline in detail the system that you used to
10 apply different weight analysis to different
11 pieces of evidence?

12 MS. PARFITT: Objection. Form.

13 THE WITNESS: And I think I
14 answered that, that there's no system
15 written down by anyone. But what
16 there is, instead, is if you read
17 these -- if you read these
18 descriptions of use of weight of the
19 evidence that I've cited in
20 paragraph 13 as well as the discussion
21 of methodology in the Canadian
22 document, that is consistent with what
23 I do. It's the idea that you start
24 with a literature search for
25 peer-reviewed, publicly available

1 information. You look at the quality
2 of the studies, the statistically
3 significant findings. Those are all
4 things that are discussed within these
5 documents I'm pointing you to.

6 QUESTIONS BY MS. BRANSCOME:

7 Q. Now, you --

8 A. But it's -- it's -- I don't
9 know of anyone who has written down a
10 specific system that applies in all
11 circumstances, no.

12 Q. Okay. Have you written down a
13 system that applies specifically in this
14 case?

15 A. I think I have tried to do that
16 for you when I describe what I did.

17 Q. Okay. You just referenced the
18 fact that your system can be found in the
19 Canadian document.

20 You agree that the Canadian
21 analysis was actually published or produced
22 after you had completed your report in the
23 MDL, correct?

24 MS. PARFITT: Objection. Form.

25 THE WITNESS: Certainly it was

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1 published afterwards, and what I
2 thought I said to you was that if you
3 look at that document -- it's not in
4 paragraph 13, but if you look at that
5 document, it lays out a process. And
6 I wouldn't call it a system. It's a
7 process. It's a process by which you
8 screen information for relevance to
9 the question being asked and how,
10 then, based on that, you look at
11 characteristics of that information
12 such as -- and I tried to give you
13 some of those.

14 And I've said this before in
15 depositions in these cases. You know,
16 you look at the issue of whether or
17 not the study was peer-reviewed,
18 whether or not there was
19 statistically -- statistical
20 significance or at least statistics
21 applied to the data. What was the
22 quality of the study as far as the
23 size in order to be able to answer the
24 question being asked. Those are the
25 kinds of things that you look at.

1 And then also the question --
2 when you're looking at a specific
3 question, you may pull in -- like you
4 asked me about the starch particle.
5 You may pull in things that you give
6 less weight because obviously that's
7 not just talc, that's starch, and you
8 have to consider that. So that is
9 part of the process.

10 QUESTIONS BY MS. BRANSCOME:

11 Q. Dr. Plunkett, the question I
12 asked you simply was: The paper that you
13 reference that contains some detail about the
14 Canadian analysis, that was published after
15 you completed your report that's marked here
16 as Exhibit 4; is that correct?

17 MR. MEADOWS: Objection.

18 THE WITNESS: Yes, and I
19 believe I answered that at the start.
20 I usually try to answer your question,
21 and then I try to explain further some
22 details I think are important context
23 on my answer.

24 QUESTIONS BY MS. BRANSCOME:

25 Q. I understand that,

1 Dr. Plunkett. You have given many
2 depositions. You understand I can ask you
3 for more detail if that would be helpful to
4 me.

5 If you could, just focus on the
6 question that I asked, and we can explore
7 additional areas if that's something I'm
8 interested in doing.

9 Okay?

10 MR. MEADOWS: Objection.

11 She's --

12 MS. BOCKUS: Break?

13 MR. MEADOWS: After I finish my
14 objection.

15 She's going to answer the
16 question as thoroughly as she feels
17 like she needs to answer the question
18 based on the way you ask it.

19 Want to take a break now?

20 MS. BRANSCOME: We can go off
21 the record.

22 VIDEOGRAPHER: We're going off
23 the record at 10:41 a.m.

24 (Off the record at 10:41 a.m.)

25 VIDEOGRAPHER: We are back on

1 the record at 10:56 a.m.

2 QUESTIONS BY MS. BRANSCOME:

3 Q. All right. Dr. Plunkett, we
4 started talking a little bit about the CIR
5 analysis that was done in 2013.

6 Am I correct you no longer
7 consider that reliable? Is that your
8 opinion?

9 A. Yes.

10 Q. Okay. And you identify in your
11 report marked as Exhibit 4, I believe it's
12 paragraph 56?

13 A. Yes, that's correct. And I
14 think I talked about it later on as well, but
15 definitely I do here.

16 Q. Okay. And in paragraph 56, you
17 state that the CIR panel failed to account
18 for all the studies that informed on the
19 issue of migration of particles such as talc
20 upwards through the reproductive tract.

21 Is that your opinion?

22 A. Yes.

23 Q. Okay. And then you state that
24 because of that you assign, quote, little
25 weight to the conclusions reached by the CIR

1 panel; is that correct?

2 A. Yes.

3 Q. And so is it your view that a
4 study or an analysis that reaches a
5 particular conclusion should be assigned
6 little weight if it fails to consider all
7 relevant scientific evidence to the issue
8 that it's evaluating?

9 MS. PARFITT: Objection.

10 THE WITNESS: I think it
11 depends on the situation, but that
12 could be the case, yes. It depends
13 on -- on the -- depends on -- I think
14 it would depend on each case, the
15 question being asked, and what was
16 omitted. But, yes, I think it could.

17 QUESTIONS BY MS. BRANSCOME:

18 Q. Okay. And in this situation
19 you identify -- I believe you claimed that
20 eight human studies were not considered by
21 the CIR 2013 panel; is that correct?

22 A. Let me look at the number, but
23 that sounds about right. Yes.

24 Q. All right. And returning,
25 actually, to your prior answer, you said that

1 the failure to consider all relevant
2 scientific evidence on a topic would lead you
3 to assign little weight to a particular
4 conclusion. You said that that could happen.

5 Under what circumstances would
6 you assign a conclusion little weight for
7 failing to consider what you consider to be
8 all relevant pieces of scientific literature?

9 A. Well, I think it depends --
10 well, the reason I specifically addressed
11 that in this case is because that was -- the
12 conclusions about migration is the main
13 reason why the CIR panel then draws
14 additional conclusions later on.

15 So my issue is, migration was
16 key to what -- the decisions they made about
17 the safety issues of talc. And so in that
18 particular case, this -- this failure to
19 consider all the evidence was extremely
20 important, in my view, and I gave it little
21 weight.

22 There might be a situation
23 where some -- for example, you may only look
24 at six or eight studies, even though there
25 may be dozens out there. You may have a

1 reason for why you only looked at six or
2 eight, or it may be -- and as a result you
3 may lay that out and, therefore, you may
4 still give weight to conclusions drawn. Or
5 it may be that the six or eight are --
6 studies that you discuss are not -- the
7 weight is not affected by what you've
8 omitted.

9 I believe that the weight is
10 affected by what is omitted when you look at
11 some of the articles being review articles,
12 which give you an understanding of what was
13 generally accepted within the scientific
14 community when you get to reviews, those
15 kinds of things. So it really is a
16 case-by-case basis.

17 But certainly I do believe that
18 it is possible that in another circumstance
19 where things are omitted you would come to
20 the same conclusion, that you give those
21 conclusions less weight.

22 Q. Is there a way, if someone were
23 try to replicate the weighting of particular
24 evidence based upon your process, for them to
25 know whether or not the omission of a

1 citation of certain studies means that a
2 study should be given little weight or
3 whether it wouldn't affect the weighting of
4 that scientific article?

5 MS. PARFITT: Objection. Form.

6 THE WITNESS: So I think this
7 is the issue of judgment, training and
8 experiencing that is applied to all
9 such assessments, and this is why
10 different scientists may come to
11 different conclusions. But certainly
12 it is -- it was important to my
13 assessment on this issue because of
14 the prominent role that the CIR report
15 gives to their conclusions here for
16 why they then drew conclusions about
17 safety. And so that link was
18 extremely important.

19 MS. BRANSCOME: Can we pause
20 for just a moment?

21 VIDEOGRAPHER: We are going off
22 the record at 11:00 a.m.

23 (Off the record at 11:00 a.m.)

24 VIDEOGRAPHER: We are back on
25 the record at 11:01 a.m.

1 QUESTIONS BY MS. BRANSCOME:

2 Q. Okay. Of the eight studies
3 that you identify on page 37 of your report
4 that you contend the CIR panel did not
5 account for, do any of those eight studies
6 specifically discuss the migration of talc in
7 human subjects?

8 A. No, I don't believe they do,
9 but there are a couple of these studies that
10 I found to be extremely important if you want
11 me to explain that to you.

12 Q. Do you break out in your report
13 in any other paragraphs which of these eight
14 articles you consider to be extremely
15 important?

16 And if you could just point me
17 to paragraph numbers, that's good enough if
18 you have, in fact, broken them out.

19 A. I have. I -- this whole
20 section I break -- I talk about each one
21 individually. So I think you can tell by
22 what I read -- what I'm discussing what I
23 thought was important and informative about
24 each of those.

25 Q. Do you rank the eight studies

1 in any way by their importance to you?

2 A. Not with any numerical rank,
3 no, but certainly I think I do that for you
4 when I talk about the studies. I give you an
5 understanding of ones that I think are
6 particularly informative and ones that are
7 not.

8 So, for example, I weight the
9 human data -- I think I tell you that -- more
10 than the animal data because of the
11 differences between the reproductive tracts
12 of humans versus animals generally, upright
13 versus -- upright and habits and things that
14 humans do that relate to insertions in and
15 out of the reproductive tract, I guess is a
16 nice way to describe it, versus an animal,
17 that those can have, and then also the
18 differences between animals and humans in
19 terms of bursal sac around the ovary, those
20 kinds of things.

21 So I do -- that -- I guess that
22 ranking I do give you here. I tell you that
23 I think these -- I think that the most
24 relevant are going to be the human studies
25 versus the animal studies.

1 Q. Right.

2 So my question specifically is,
3 where would you point me to in your report to
4 understand the weight that you gave each of
5 these particular eight studies?

6 A. At my descriptions of those
7 studies and what I describe. That's all I
8 can tell you.

9 Q. And I'm just asking,
10 Dr. Plunkett, can you point me in the report
11 to where that discussion takes place?

12 A. It takes place -- I have a
13 discussion for each study, and I would -- and
14 if you read what I say about each study, I
15 try to go through what the strengths and
16 weaknesses of those studies are.

17 And so those -- that would be,
18 let's see -- you want me to give you the
19 starting paragraph?

20 Q. So, for example, Parmley and
21 Woodruff. Can you point me to where in your
22 report you discuss Parmley and Woodruff, such
23 that I can understand the weight that you
24 gave that particular study?

25 A. So the year of it is...

1 So I think I discuss it in
2 paragraph 44, and so I describe for you what
3 important information is in there, which is
4 the information that I take as forming part
5 of my weight of the evidence.

6 So one of the most important
7 things is what -- they have a figure they
8 show, and they're showing -- which is one of
9 the unique figures in all of the published
10 literature. But it talks about the
11 differences between the female reproductive
12 tract and the male reproductive tract, and it
13 shows the actual -- it talks about a
14 discussion of movement from substance in the
15 environment through -- into the vagina, into
16 the fallopian tubes. So it's a paper that
17 addresses that very specific issue.

18 Q. So my question to you, though,
19 is, where do you have a discussion of the
20 weight that you give to these particular
21 articles?

22 A. So the discussion of the weight
23 has to do with the information described. I
24 don't give them a numerical ranking. I told
25 you that.

1 So what I do is, when I'm
2 discussing about these -- all of these papers
3 here contribute to my weight of the evidence.
4 And if it's a human study, I'm giving those
5 more weight than I'm giving animal studies.
6 And that's described.

7 And then within papers I'm
8 pulling out information that contributes to
9 what I think is important about what the
10 study says, and that -- and the importance of
11 what is described within the study
12 contributes to my weight.

13 And I don't know how else to
14 describe it to you. That is the process that
15 scientists go through when they evaluate
16 data.

17 Q. And so my question to you:
18 Earlier you said of these eight studies, some
19 of them were particularly important to you.

20 How would I, using only what's
21 written in your report, understand which of
22 those eight studies was of particular
23 importance to you?

24 A. So it would have to do with
25 what I discuss about the study. So I'm

1 telling you, when I -- if you look through
2 this entire section, this is the Parmley and
3 Woodruff paper. It is important because it
4 addresses the specific issue of movement of
5 environmental substances from the outside to
6 the inside. So I'm giving that importance in
7 my evaluation because of what that author is
8 actually discussing.

9 I don't know how else to
10 describe that. I apologize. I mean, to me,
11 weight of the evidence is a process that
12 scientists use bringing their training and
13 experience and judgment, and it's not a
14 numerical process across the board, it just
15 is not, based on the way weight of the
16 evidence is used within science.

17 Q. Now, Dr. Plunkett, though, you
18 would acknowledge that if you wanted to
19 assign numerical values to the studies, that
20 has been something that has been done by
21 other authors and other authors on whom you
22 rely, correct?

23 MS. PARFITT: Objection. Form.

24 THE WITNESS: I don't believe
25 that's true. I'll need to look -- I

1 don't believe that's true with respect
2 to the biological information. I
3 believe it may be true with respect to
4 the epidemiology studies.

5 You want me to look real quick
6 to confirm that? I can do that really
7 quick, but...

8 QUESTIONS BY MS. BRANSCOME:

9 Q. I'm simply saying, could you
10 assign a numerical value if you chose to do
11 so?

12 MR. MEADOWS: Objection.
13 Objection. Form.

14 THE WITNESS: And I'm -- what
15 I'm trying to say to you is I think
16 that I -- that there is no one set of
17 rules that you would assign in order
18 to do that for all the types of
19 studies that you weigh.

20 I would agree that I have seen
21 it routinely done -- well, not
22 routinely, but I've seen it done
23 within the epidemiological community
24 when they go through the epi data.
25 But not -- it's not something that

1 I've seen done when you talk about
2 weight of the evidence as part of a
3 human health risk assessment. That is
4 not something that scientists
5 typically do as far as giving
6 numerical rankings.

7 QUESTIONS BY MS. BRANSCOME:

8 Q. You're familiar with the
9 National Cancer Institute, correct?

10 A. Yes, I am.

11 Q. All right. They are considered
12 to be the nation's leader in cancer research,
13 correct?

14 MS. PARFITT: Objection to
15 form.

16 THE WITNESS: The National
17 Cancer Institute?

18 Yes, they are. I don't know if
19 they're "the" leading, but they're one
20 of the leading, that's true.

21 QUESTIONS BY MS. BRANSCOME:

22 Q. Okay. And you're familiar with
23 publications that they issue called physician
24 data queries?

25 A. Yes, I am.

1 Q. All right. And you are aware
2 that there is, in fact -- called PDQs,
3 correct?

4 A. That's the abbreviation, yes.

5 Q. Right. And you're aware that
6 the National Cancer Institute has in fact
7 published a PDQ that addresses a potential
8 connection between talc and ovarian cancer,
9 correct?

10 A. I'm aware of several that have
11 been done over the years, but, yes, I'm aware
12 of that.

13 Q. And have you reviewed those?

14 A. Yes, I have.

15 Q. Are they listed on your
16 reliance list?

17 A. No, but they're listed within
18 the materials as discussed within my
19 depositions, and I thought -- and my
20 testimony. I thought that was part of my
21 reliance list. I believe that it -- it was
22 in my reliance list, is encompassing all of
23 the testimony as well as the actual
24 documents. Maybe I'm mistaken, but that was
25 my understanding.

1 Q. Okay. If they are not on your
2 reliance list, should they be?

3 A. I believe that they are on my
4 reliance list by it having been pointed to as
5 part of the testimony that I have given and
6 the documents that I have relied upon during
7 testimony.

8 Q. Okay. And you are aware that
9 they have issued a PDQ that -- on the website
10 as of today, correct?

11 A. I haven't looked today, so I'm
12 sure -- but I know that -- I don't believe it
13 has been removed, so I believe that there is
14 something there, yes.

15 Q. All right. And what is your
16 understanding of the position stated in the
17 PDQ with respect to a possible link between
18 talc and ovarian cancer?

19 A. So I'd have to look at the one
20 today to tell you what it says, but it's
21 evolved over time and it's changed over time,
22 and I have specific opinions that I've
23 expressed at trial about that issue.

24 Do you want me to go into that
25 details or I mean --

1 Q. I'm not asking about your
2 opinions about what their position is. I'm
3 simply asking you, Dr. Plunkett, the most
4 recent NCI PDQ that you have reviewed, what
5 is the position that the National Cancer
6 Institute has taken with respect to the
7 relationship between talc and ovarian cancer?

8 A. So I would want to pull it out
9 to give you the specific statement of their
10 position, but their position has changed such
11 that later in time they've weakened the
12 link -- their statements about the link
13 between ovarian cancer and genital talc use.

14 So it used to be seen as a
15 cause, and now I believe it's not seen as a
16 cause. I don't know the exact language,
17 though. I'd have to look at it as -- maybe
18 risk factor is the better word to use.

19 And I need to look at the most
20 recent one. And that would be the best way.
21 Let's just see what it says.

22 Q. Okay. 'Cause is it your
23 position as you sit here today that the
24 National Cancer Institute has ever issued a
25 statement that talc causes ovarian cancer?

1 A. I believe it was listed as a
2 risk factor for ovarian cancer in the older
3 PDQs.

4 (Plunkett Exhibit 7 marked for
5 identification.)

6 QUESTIONS BY MS. BRANSCOME:

7 Q. I do have a copy here. Just
8 for the sake of the record, we will mark this
9 as Plunkett Deposition Exhibit Number 7.

10 Handing a copy to you,
11 Dr. Plunkett, do you recognize the document
12 that I just handed you that's marked as
13 Exhibit 7?

14 MR. LOCKE: What's the date of
15 that?

16 MS. BRANSCOME: This was
17 printed on December 14, 2018.

18 THE WITNESS: It's -- the
19 updated date is June 22, 2018, if that
20 helps.

21 MR. LOCKE: Yes, thank you.

22 THE WITNESS: I have seen this
23 one, yes.

24 QUESTIONS BY MS. BRANSCOME:

25 Q. All right. And you can review

1 any -- whatever portion of this is helpful to
2 you.

3 And then if you could answer my
4 question, Dr. Plunkett, of what is the
5 position as stated in Deposition Exhibit
6 Number 7 of the National Cancer Institute
7 with respect to the relationship between talc
8 and ovarian cancer?

9 A. So I would be looking at the
10 section on page 12 of 18, and maybe you're
11 looking somewhere else, but that's where they
12 actually talk about perineal talc exposure.
13 And it's under the section where they have
14 now moved into factors with an adequate
15 evidence of an association and they describe
16 it here. So they're calling it an
17 association where the weight of the evidence
18 is not adequate to support that association.

19 Q. All right. And so the first
20 sentence of the section under perineal talc
21 exposure states, "The weight of the evidence
22 does not support an association between
23 perineal talc exposure and an increased risk
24 of ovarian cancer."

25 Did I read that correctly?

1 A. You did read that correctly.

2 Q. All right. And it indicates
3 that "results from case-control and cohort
4 studies are inconsistent."

5 Did I read that correctly,
6 Dr. Plunkett?

7 A. You did.

8 Q. And the question that I would
9 ask simply is, do you discuss the National
10 Cancer Institute PDQ in the report that
11 you've issued in the MDL, which is identified
12 as Exhibit 4?

13 A. I don't specifically discuss
14 this document, no, I do not.

15 Q. Okay. And you understand that
16 the NCI PDQ did a weight of the evidence
17 analysis that followed a formal evidence
18 ranking system, correct?

19 MS. PARFITT: Objection.

20 THE WITNESS: So I -- it's not
21 laid out here, but they do have a
22 process they use.

23 Is that what you're asking me?

24 QUESTIONS BY MS. BRANSCOME:

25 Q. Yes.

1 A. Yes. And again, they're
2 ranking the epidemiological data, and so I
3 understand that that is there, yes.

4 Q. Now, you've said a few times
5 that you could qualitative -- you could give
6 a quantitative weight to an epidemiological
7 study, somehow suggesting that it is
8 different from other types of studies.

9 What is it about a
10 toxicological study, for example, that would
11 prevent someone from giving a quantitative
12 weight in a weight of the evidence analysis?

13 A. Because it is just what is
14 typically done and not done. There are
15 certain practices within the community, what
16 is kind of -- I would say that scientists use
17 routinely, or scientists have used. Not all
18 scientists give numerical rankings to
19 epidemiological data either, because even
20 within a Bradford Hill assessment, when you
21 use the considerations, there's no
22 requirement for ranking studies in order to
23 meet the requirements of use of that
24 methodology.

25 Q. Okay.

1 A. But I have seen it done in the
2 epidemiology community, and that is the most
3 common place I see it. I do not see other
4 toxicologists that are assessing animal
5 studies and in vitro studies doing it that
6 same way.

7 When you do a human health risk
8 assessment, that isn't routine practice to do
9 numerical rankings on studies.

10 Q. Okay.

11 A. At least in my experience and
12 in my training, and I was trained in the use
13 of risk assessment by one of the individuals
14 who actually invented the process.

15 Q. Okay. Okay. But do you
16 consider the epidemiological evidence as part
17 of your risk assessment in the MDL?

18 A. I do, because I'm looking at it
19 in the context of what is out there and
20 what's available. I don't always have human
21 data when I do risk assessments, but in this
22 one I do. So I do consider them, yes.

23 Q. Okay. Did anything prevent you
24 from doing a quantitative assessment of the
25 weight that you were giving different pieces

1 of epidemiological evidence?

2 A. If by -- you mean prevent, was
3 someone stopping me from doing that, no. But
4 if you ask what would be standard practice
5 based on my experience, I would not be doing
6 that.

7 Q. Has anyone -- and I'm not
8 referring in this case to any attorneys. But
9 has anyone reviewed your -- the weighting
10 that you gave specific pieces of evidence as
11 essentially a form of a peer review process?

12 A. If by that you mean have I
13 submitted my opinions for publication, no, I
14 have not done that. Part of -- that's partly
15 driven by my understanding of the evidence
16 that I reviewed, that some of it may not be
17 something that I should be discussing
18 necessarily in a public form outside of the
19 cases I'm working in.

20 But certainly I have not
21 submitted it for publication, if that's what
22 you mean. No, I have not done that.

23 Q. Okay. Has the methodology that
24 you have used in the MDL, has that been --
25 have you submitted any type of analysis using

1 that methodology for publication even outside
2 of particularly looking at Johnson's baby
3 powder, for example?

4 A. Yes, in -- if you look at my
5 publications that describe risk assessments
6 that I have done. So the one that would come
7 to -- to play that's similar as far as the
8 scope of the weight of the evidence would --
9 at least with the animal and the in vitro
10 studies, would be the paper that I published
11 on copper, looking at the database of copper
12 and identifying points of departure and
13 target organs and risk -- risk issues based
14 on copper use in humans, trying to set a --
15 understand what a safe exposure level could
16 be to copper in water. And that was
17 published -- that actually was one of the
18 papers that's published with Dr. Krewski, who
19 is one of the authors of this risk assessment
20 in Canada.

21 Q. And is it your position that
22 you follow the same methodology in what
23 you've reported in the MDL with respect to
24 Johnson's baby powder that you did in your
25 analysis of copper?

1 A. Yes, with the process of going
2 through all of the publicly available
3 information, putting it together based on its
4 relevancy and reliability.

5 We did a process where we
6 grouped it based on animal versus human, just
7 like I've done here. And we call it the
8 bins, but it's the same idea. I have a bin
9 of human idea, I have a bin of animal data
10 and a bin of in vitro data. And so, yes, the
11 process was very, very similar.

12 Q. Okay. Returning back to some
13 documents that you chose not to cite in your
14 report, you do not discuss the Gonzales 2016
15 study in your report for the MDL, correct?

16 MS. PARFITT: Objection. Form.

17 THE WITNESS: I'll have to
18 look. It is not cited in the
19 reference list to my report, that is
20 true. So that means it would not be
21 mentioned specifically in the body of
22 the report.

23 QUESTIONS BY MS. BRANSCOME:

24 Q. You're familiar with the
25 Gonzalez 2016 study, correct?

1 A. If you want me to talk about
2 it, you'd have to pull it out for me, but I
3 know the name, yes.

4 Q. Okay. And it was looking at an
5 association between the perineal use of talc
6 and ovarian cancer, correct?

7 A. That, I'd have to look at it to
8 tell you. I believe it was a human study
9 that would be consistent with that, but I
10 need to pull it out to look at it.

11 Q. All right. Do you, as you sit
12 here today, do you know why you did not
13 discuss it in your report?

14 A. I wasn't doing a full causation
15 analysis in this report, so as a result I'm
16 not trying to characterize every piece of
17 human data. But I certainly am looking at
18 the consistency across the studies, and
19 that's what I've done.

20 And I mention it here. I do
21 think I mention here that there are studies
22 that came to different conclusions than the
23 ones that I'm specifically describing.

24 Q. Okay. And so why is it that --
25 why is it acceptable for you to choose not to

1 include something like the Gonzales 2016
2 study, but yet you will disagree the
3 2013 -- the CIR 2013, you will give it little
4 weight for not discussing particular studies?

5 A. So that's a very different
6 exercise. You want me to explain my thinking
7 on that? I can do that for you, but I
8 believe that's apples and oranges question.

9 My reasons for giving little
10 weight to the CIR overall assessment versus
11 my weight or the assessment I make of an
12 individual piece of data, that's different.
13 And that's what you're describing for me.

14 And I believe Gonzales is in my
15 overall reliance list, so I have read
16 Gonzales. It is something that I have
17 considered; it's not something that I've
18 cited in my paragraphs. So it doesn't mean
19 it didn't go into my weight of the evidence,
20 because I do have it and I have reviewed it.
21 I just don't recall the details on it.

22 Q. Is it your position as you sit
23 here today that you know for sure that the
24 CIR panel did not -- was not aware of or even
25 considered any of the eight studies that you

1 contend the omission of which makes it of
2 little weight?

3 MS. PARFITT: Objection. Form.

4 THE WITNESS: I would say I'm
5 99.9 percent sure, based on the
6 process that is -- that goes in. And
7 if you want me to explain, I'll tell
8 you why I feel that level of surety.

9 You know, I can always say that
10 maybe there was someone that came to
11 the panel that did a search on their
12 own, but that is not what's done. The
13 individuals that come to the panel are
14 given a body of information provided
15 to them in written form that they
16 review. So it's not like they -- they
17 have access to anything that isn't
18 cited in the actual report.

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Okay. The eight articles that
21 you discuss that are not mentioned in the CIR
22 panel's work, they are publicly available
23 pieces of scientific literature, correct?

24 A. Yes, which was why it's
25 interesting to me that those were not grabbed

1 and included within -- within the assessment
2 done by the -- by the PCPC's group that
3 handles CIR -- handled the CIR process here.

4 Q. Okay. We received just before
5 your deposition, a few days in advance, a
6 list of materials that have been added to
7 your reliance list since you produced your
8 report in this case.

9 Did you provide that list of
10 materials to counsel to -- are you aware of
11 the materials that were identified?

12 A. Yes, I am. They're ones that I
13 have reviewed since my report and -- yes,
14 which would have been, I believed, important
15 for you to know about, because obviously you
16 wouldn't know if I hadn't provided that to
17 you, and fair game for you to ask me about.

18 Q. On that list was contained a
19 number of news articles.

20 A. Uh-huh.

21 Q. Are news articles pieces of
22 scientific information that you typically
23 consider in performing a risk assessment?

24 A. No, they're not part of my risk
25 assessment, but they -- but they were

1 relevant to -- they were relevant to my
2 overall assessment of the issue of what the
3 company is doing with regard to public
4 dissemination of information.

5 So it's not the risk assessment
6 part. It's more on the issue of the -- when
7 I talk about the different influences of the
8 company on public dissemination of
9 information, I went through the different
10 specific issues. So this would be a specific
11 issue related to a news report that someone
12 comes out with, the Reuters report, and then
13 looking at what the company is saying in
14 addition to that.

15 So it's understanding -- for
16 example, the documents that Reuters
17 discusses, many of those I'm sure I have
18 seen, although I don't have access to -- I
19 wasn't able to go on websites and download
20 everything that they cite. But certainly
21 they looked familiar, some of the ones I did
22 see.

23 So it's that issue of -- the
24 last part of my report, I think. Want me to
25 tell you the section? It would be in the

1 section on the role of the industry in
2 Section 7.

3 Q. Okay. So the newspaper
4 articles are not something that you are
5 considering as part of your analysis of
6 whether there is a risk of ovarian cancer
7 from Johnson's baby powder, correct?

8 A. No, that's a separate issue
9 because it's not -- it's not scientific data,
10 per se.

11 Q. Okay. All right. Now, if you
12 could turn to paragraph 31 in your report.

13 Okay. You discuss the
14 biological effects of talc in this paragraph
15 and in others, correct?

16 A. Yes, I would call this my
17 introductory paragraph to transition into a
18 specific topic, yes.

19 Q. Okay. And you talk here about
20 the structure and size of talc affecting its
21 properties.

22 What do you mean by that?

23 A. So whether it's fibrous enough,
24 platy, fibrous. Whether it is particle sizes
25 of less than 10 microns, less than 5 microns,

1 greater than 75 microns. There's
2 different -- certain pieces of literature
3 deal with different size ranges of talc. The
4 smaller the size range, the more toxic it is,
5 for example, to lung tissue; the more likely
6 it is to be able to move, based upon the
7 size, versus being engulfed by a macrophage
8 if it's a larger particle, things like that.

9 Q. So focusing specifically on
10 ovarian cancer, what role does size and
11 structure of a talc particle play with
12 respect to a risk of ovarian cancer in your
13 opinion?

14 A. I don't think I formed a
15 opinion that it has to be a specific size or
16 structure, because the -- my opinions are
17 related to the fact that we have a complex
18 mixture of ingredients within the body
19 powder, and my assessment's been on the
20 overall consumer product, not on any one
21 particular ingredient only within it.

22 So it's the idea of just
23 understanding that size and structure of
24 these particles are general principles that
25 affect toxicology. So a larger particle or a

1 fibrous particle may have a different tissue
2 toxicity response than a smaller particle.

3 So in other words -- I think I
4 discuss this later in a paragraph about
5 pleurodesis, the idea that you can get acute
6 versus chronic inflammation, or respiratory
7 distress or not. So it's just this idea of a
8 general principle that outlines how you would
9 think about particles generally as a
10 toxicologist.

11 Q. Well, okay. So you said that
12 your assessment is based on the overall
13 consumer product. That would be Johnson's
14 baby powder or SHOWER TO SHOWER®, correct?

15 A. Yes.

16 Q. All right.

17 A. Or Shimmer. I think that's the
18 other name. There's a third product.

19 Q. Okay. But my question to you
20 is, you actually cite a number of pieces of
21 literature in the section about the alleged
22 toxicity of talc that don't relate to the
23 overall consumer products at issue in this
24 case, correct?

25 MS. PARFITT: Objection. Form.

1 THE WITNESS: No, I would
2 disagree with that when you use the
3 word "relate." Relate to me means is
4 it relevant to the assessment, and
5 they are, even if they're not just on
6 the finished product.

7 But if what you mean is that
8 there are studies that did not test
9 the consumer product but individual
10 ingredients or -- that is true, yes,
11 but all of that is relevant or relates
12 to the overall risk assessment.

13 QUESTIONS BY MS. BRANSCOME:

14 Q. Okay. So given your view that
15 information about the individual constituents
16 is relevant to evaluating the overall
17 toxicity of the ultimate consumer products,
18 then my question to you is: How does the
19 structure and size of the component talc
20 particles play a role in toxicity with
21 respect to ovarian cancer?

22 A. Just generally -- it's not
23 just -- well, with respect to ovarian cancer,
24 we start with irritation, inflammation
25 potential. Size of particles and shape are

1 known to affect tissue toxicity as far as
2 adverse events like inflammation and/or
3 irritation.

4 Q. Okay. So that's -- that's what
5 I'm trying to understand in more detail.

6 What is your opinion with
7 respect to -- let's take size to start with.
8 Is there a particular size talc particle that
9 is more or less likely to cause inflammation,
10 in your opinion?

11 A. It depends whether you're
12 talking about acute or chronic. I would say
13 for acute inflammation the larger particles,
14 such as some of the particle sizes that are
15 used in the pleurodesis products, are more
16 likely to initiate an acute inflammatory
17 response due to the fact that they're large
18 enough that the body will recognize them with
19 a fairly robust foreign body response.

20 Q. What is your definition of
21 large?

22 A. So the literature varies, but
23 certainly particles that are above -- some of
24 the literature talks about particles that are
25 in the range of 25 to 75. Some of them talk

1 about larger particles even than that.

2 It has to do with the fact
3 that -- this is complicated by the fact that
4 any consumer product -- or any talc sample
5 will have a range of sizes because they don't
6 select for one size. They select for smaller
7 than. So a 200 mesh, a 400 mesh, that has do
8 with what will filter through.

9 So pleurodesis, they try to
10 avoid for those products the really small --
11 large amounts of less than 10 because that
12 leads to respiratory distress, whereas many
13 of the consumer talc products are using much
14 smaller, finer particles to get that feel and
15 performance they want from the consumer body
16 powders.

17 Q. Have you reviewed -- focusing
18 specific on Johnson & Johnson's products,
19 have you reviewed the documents that relate
20 to the specifications for the Johnson's
21 products with respect to the size of the
22 plate particles?

23 A. I have seen those, yes. I
24 can't tell you what each of them says without
25 pulling them out, but, yes, that is certainly

1 documents I have seen and relied upon.

2 Q. Is it consistent with your
3 understanding that it was Johnson & Johnson's
4 intention to select large platy talc
5 particles for its products?

6 MS. PARFITT: Objection to
7 form.

8 QUESTIONS BY MS. BRANSCOME:

9 Q. Have you seen that in the
10 documents?

11 A. I don't know that it's
12 described quite that way, but they certainly
13 were doing a 200 mesh selection. So -- for
14 their body powders products. So -- and they
15 were trying -- and they did make attempts to
16 look for sources that were more platy talc
17 than other forms, but that doesn't ensure
18 that everything is platy talc.

19 Q. Are you familiar with the term
20 "fines"?

21 A. Yes, generally, but I'm not --
22 but I'm not an expert in the processing of
23 talc as far as how you would go about
24 choosing an ore or a mine. There's others
25 that will be addressing that. That's not my

1 area.

2 Q. What is your understanding of
3 the term "fines"?

4 A. My understanding of the term
5 "fines" has to be looking for a sample or a
6 group that has been processed such that it
7 has certain characteristics.

8 Other than that, I would refer
9 you to the individuals in litigation that are
10 going to be dealing with the processing.

11 Q. Okay. Have you taken into
12 account in your analysis in any way the
13 beneficiation process that occurs between the
14 time that the talc is mined and it ends up in
15 one of the consumer products that is relevant
16 to your analysis?

17 MR. MEADOWS: Objection.

18 THE WITNESS: So what do you
19 mean by taking it into account? Am I
20 aware that they have something that's
21 in place for that? Yes.

22 But take into account, what do
23 you mean by that?

24 QUESTIONS BY MS. BRANSCOME:

25 Q. Are you familiar with the

1 effects that beneficiation can have on the
2 level of the component -- the components in
3 talc and what ultimately ends up in one of
4 Johnson & Johnson's consumer products?

5 MR. MEADOWS: Objection.

6 THE WITNESS: So I'm not -- I'm
7 not familiar with all the details, but
8 I am familiar that it is a process
9 they're using to attempt to result in
10 a product that has characteristics
11 that would be desirable for a consumer
12 product.

13 Again, there is my
14 understanding that others are going to
15 be discussing the geology or the
16 processing, and that is not something
17 I'm looking at.

18 The literature as it relates to
19 what has been tested in the public
20 literature in particular, and that
21 would be either an ingredient or a --
22 or a consumer product or a -- they may
23 discuss exposure occupationally to
24 mining or milling, which is -- which
25 is an issue that you can consider when

1 you're reviewing that literature as
2 well.

3 QUESTIONS BY MS. BRANSCOME:

4 Q. Okay. And so when you cite --
5 for example, you have a significant number
6 of -- I'm trying to find the right paragraph.

7 You have a section in your
8 report where you discuss a number of
9 different articles that relate to talc, and
10 in parentheses you identify that the talc
11 source might be cosmetic, it might be
12 industrial, things of that nature, correct?

13 A. Yes, I do that on purpose
14 because I wanted -- I did look at the
15 literature to understand what they were --
16 what they were -- what type of exposure they
17 were describing.

18 Q. Okay. And so understanding
19 that some of those products are not
20 representative of what ultimately is in
21 Johnson's baby powder, do you have anything
22 in your report that explains how you did or
23 did not give weight to those particular
24 studies?

25 MS. PARFITT: Objection. Form.

1 THE WITNESS: Let me look and
2 see what I say.

3 If the question has to do with
4 numerical rankings, no, I did not do
5 that. But you're asking something
6 else, right, broader than that,
7 correct?

8 QUESTIONS BY MS. BRANSCOME:

9 Q. The question that I have is,
10 how did -- is there somewhere in this report
11 that I can understand the weight that you
12 assigned to say a study that related to
13 industrial talc as opposed to information
14 about cosmetic talc, for example?

15 MR. MEADOWS: Objection.

16 THE WITNESS: So I -- I'm -- I
17 believe I address that. I don't know
18 it's exactly answering your question,
19 but I lay out for you the
20 characteristics of the literature in
21 paragraph 37, and I point out that the
22 scientific literature varies.

23 And the fact -- and I point --
24 and I admit -- I'm not admitting. I'm
25 stating the fact that in some cases

1 the authors will not describe it
2 specifically as the type of talc, but
3 just talc, whereas -- with no
4 description of purity or state, for
5 example. But in cases where the
6 literature does, I did consider that
7 in my weight of the evidence.

8 So, for example, when I -- when
9 I lay it out here in these bullets
10 where I'm putting for you tremolite
11 mining industrial grade cosmetic, it
12 certainly is something that I weighed.
13 And obviously as much information as I
14 can get on cosmetic-grade talc is
15 going to be most important in the
16 assessment, but that doesn't mean the
17 other information isn't relevant.

18 You want me to explain why?

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Well, so, for example, you
21 describe the Dreessen article that related to
22 trimellitic talc that's mined out of
23 New York.

24 You would agree that
25 trimellitic talc from New York is not

1 something that ever ended up in Johnson's
2 products, correct?

3 MR. MEADOWS: Objection.

4 THE WITNESS: I don't think I
5 can answer that yes or no. I haven't
6 done an assessment to see whether it
7 ever ended up in the products. That's
8 a different question.

9 I certainly am aware of the
10 fact that was not a primary source of
11 their talc, that is true. I do know
12 that.

13 In other words, I don't have
14 records from -- going back from 1894
15 on what the source of their talc was.
16 So I can't tell you over time.

17 What I do know, what's been put
18 into depositions and testimony of
19 company employees more recently, where
20 it's my understanding that the
21 principal sources over the years were
22 either the Vermont mine, the Italian
23 mine or the Chinese mine. And there
24 were different interruptions in time
25 where different mines were used,

1 depending on sourcing.

2 QUESTIONS BY MS. BRANSCOME:

3 Q. So as part of your expert
4 analysis where you are evaluating articles
5 that relate to different types of talc from
6 different sources of talc, have you done an
7 analysis of how those particular types of
8 talc do or do not relate to what is in the
9 consumer product manufactured by Johnson &
10 Johnson?

11 MS. PARFITT: Objection. Form.

12 THE WITNESS: The first part of
13 your question, again? I'm sorry.

14 MS. BRANSCOME: Would you read
15 it back?

16 THE WITNESS: Could you read it
17 back to me again? I didn't mean to
18 wander, but the first few words I
19 missed.

20 (Court Reporter read back
21 question.)

22 THE WITNESS: Okay. So I
23 certainly did, which is why I'm
24 breaking this out here for you this
25 way.

1 So I am -- I am certainly
2 recognizing, and I analyzed on the
3 paper -- through the papers what type
4 of product, if available, that the
5 data is on.

6 But if you read my report in
7 the process of risk assessment, all of
8 these categories of papers are
9 relevant to telling you something
10 about what talc can do. And then when
11 you talk about drawing final
12 conclusions, I'm looking for
13 information, if I can, and I have it,
14 that is on point to the product that
15 was sold.

16 So certainly the studies that
17 give me information on cosmetic-grade
18 talc are extremely important to my
19 assessment, and they're ones that I've
20 discussed or we've even used in trial
21 before when we've talked about putting
22 together a timeline.

23 That's what this is about, by
24 the way. This discussion here, I'm
25 starting to lay out what information

1 was available over time, and that's
2 simply what this is. It's a survey of
3 the literature that talks about
4 adverse effects of talc, and if I can,
5 I separate it into different qualities
6 or purities.

7 QUESTIONS BY MS. BRANSCOME:

8 Q. Dr. Plunkett, respectfully, I
9 don't believe you answered my question.

10 Can you point me to anywhere in
11 your expert report that's been produced in
12 this MDL where you do an analysis of how the
13 different talc types and sources that you are
14 citing as support for the toxicity of talc
15 generally relate to the products manufactured
16 by Johnson & Johnson?

17 MR. MEADOWS: Objection.

18 THE WITNESS: So I don't know
19 how else to answer that but to tell
20 you I think that's what this whole
21 section is about. I step you
22 through -- I identify different types
23 of evidence. I identify for you what
24 was tested in those different pieces
25 of evidence, and then I step through

1 that to draw conclusions based upon
2 what was available for me to assess.

3 QUESTIONS BY MS. BRANSCOME:

4 Q. Okay.

5 A. I don't know how else to answer
6 it for you. That's what the section is meant
7 to do, and that's why I broke it out that
8 way. You know, I recognize that there is
9 data on different things.

10 What's interesting about even
11 the data on different things, there's a
12 common mechanism that is involved with the
13 type of tissue toxicity you get, and that's
14 irritation and inflammation. Regardless of
15 whether it is of a certain grade or not, you
16 get certain types of adverse reactions. May
17 be a more sustained reaction with a
18 industrial grade versus cosmetic grade, but
19 they all have the capability to produce that
20 type of adverse effect.

21 Q. Dr. Plunkett, where can you
22 point me to in your report that you discuss
23 the weight that you give studies that relate
24 to talc from New York as opposed to studies
25 that relate to cosmetic talc that ultimately

1 ended up in Johnson's baby powder?

2 MS. PARFITT: Objection. Form.

3 THE WITNESS: I've tried to
4 answer that for you. The weight that
5 I'm giving -- the weight that I'm
6 giving is part of my assessment. So,
7 again, I don't give numerical
8 rankings. I've answered that for you.
9 I don't do that.

10 What I instead do is I'm
11 looking at everything that's relevant,
12 everything that's available. I do
13 categorize it, so I am selecting -- I
14 am identifying or analyzing the
15 information for what it describes.
16 And then if you go further on down, I
17 try to tell you what I think is
18 important about that information.

19 The overall conclusions I'm
20 drawing in the report, though, when I
21 cite to specific studies in the risk
22 assessment, the majority of those
23 studies I believe that I'm citing for
24 you, outside of notice, have to do
25 with -- that's more of a warnings

1 issue -- have to do with the issue of
2 cosmetic talc. Because the human
3 studies are describing cosmetic talc.
4 The NTP studies is a pure talc. Many
5 of the in vitro studies and other
6 animal studies are looking at,
7 quote/unquote, a talc that is not an
8 industrial grade or from a mine that
9 would have -- be looked at in that
10 way. So --

11 QUESTIONS BY MS. BRANSCOME:

12 Q. You understand that there are
13 different types of cosmetic talc, correct?

14 A. Yes, I am aware.

15 Q. And cosmetic talc can be mined
16 from a number of different mines globally,
17 correct?

18 A. That's correct.

19 Q. And some of the studies that
20 you cite in your report are testing cosmetic
21 talc from other consumer products, for
22 example, Cashmere Bouquet, correct?

23 A. Some. The majority of them are
24 not, but I would agree that some do, yes.

25 Q. Okay. Have you done an

1 analysis of how the talc that is used in
2 Cashmere Bouquet, for example, relates to the
3 talc that is used in Johnson's baby powder?

4 Is that an analysis that you
5 have done before relying on that information
6 in your report?

7 MR. MEADOWS: Objection.

8 MS. PARFITT: Objection.

9 THE WITNESS: My analysis -- I
10 did do an analysis to look at what was
11 described, what products are
12 described, but I certainly -- I
13 certainly did not throw out studies
14 that described Cashmere Bouquet
15 because I would -- I still believe as
16 a toxicologist and a risk assessor
17 that those types of products are
18 important to the overall weight of the
19 evidence about the hazard and the
20 risks posed by talc.

21 You know, I just -- I just -- I
22 guess I disagree with you if you're
23 saying they're irrelevant. I don't
24 believe that they are.

25

1 QUESTIONS BY MS. BRANSCOME:

2 Q. I was simply asking: Did you
3 do an analysis that would allow you to
4 compare the ingredients in another product,
5 like consumer Cashmere Bouquet, before you
6 rendered an opinion with respect to Johnson's
7 baby powder based on tests of Cashmere
8 Bouquet? Did you do that analysis?

9 MR. MEADOWS: Objection.

10 THE WITNESS: I do not have
11 access to internal company documents
12 for the manufacturers of Cashmere
13 Bouquet, so I certainly couldn't do
14 the analysis in the same way that I
15 can do it here, where I can identify
16 what Johnson & Johnson and Imerys
17 describe as sources of the talc that
18 was used for the Johnson & Johnson
19 baby powder, without --

20 QUESTIONS BY MS. BRANSCOME:

21 Q. So you have no way of knowing
22 one way or the other whether that talc is
23 similar, correct?

24 MR. MEADOWS: Objection.

25 MS. PARFITT: Objection.

1 THE WITNESS: Well, I think I
2 do know it's similar, if you look on
3 the bottle as far as what is described
4 it being, but if you're asking me --
5 if you're asking did we fingerprint it
6 to only a particular mine, this is the
7 beauty of the data. The data shows
8 that regardless of the type of product
9 you're looking at, there's consistency
10 across the study.

11 So -- but I did not try to
12 segregate out studies that only dealt
13 with Cashmere Bouquet, no, I did not
14 do that.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. Okay. As you sit here today as
17 a toxicologist, is it your position that
18 industrial-grade talc that might contain up
19 to 70 percent tremolite presents the same
20 level of toxic effect as cosmetic talc that
21 may contain no tremolite or tremolite at a
22 very, very low level?

23 MS. PARFITT: Objection. Form.

24 THE WITNESS: I haven't formed
25 that opinion, no.

1 QUESTIONS BY MS. BRANSCOME:

2 Q. Okay. And so have you formed
3 an opinion that I could find in your report
4 that discusses in any way the relative
5 toxicity of different types of talc?

6 A. That, you may find. I need to
7 go back and look how I set it out, but I
8 think I -- I talked with you about the
9 difference between fibrous versus platy. I
10 do discuss that.

11 And I talk about the problems
12 when you have a complex mixture that has
13 added to it things like asbestos and heavy
14 metals, because I talk about the additivity
15 issue that can come to play. So that -- in
16 other words, increased risk when you have a
17 complex mixture with additional components
18 that all share the same toxic properties as
19 far as target organs or types of effects or
20 mechanisms that are triggered in the body.
21 That's what I point you to.

22 I -- I don't -- that's the only
23 way I can answer that for you, I think, based
24 on what I know I have in here.

25 Q. Okay. You talk about the term

1 "asbestiform talc."

2 You talk about asbestiform
3 talc.

4 Are you familiar with that?

5 A. I do mention that in my report,
6 yes.

7 Where are you?

8 Q. At paragraph 30. It's on
9 page 19 of your report.

10 A. Yes, I'm here.

11 Q. Okay. And the first sentence
12 in paragraph 30 you state, "In the published
13 medical literature, there is often discussion
14 of talc using terms such as fibrous talc,
15 asbestiform talc, non-asbestiform talc or
16 tremolite."

17 Do you see that?

18 A. Yes, I do.

19 Q. Okay. Is it your opinion that
20 tremolite is a form of talc?

21 A. So tremolite is a -- is a -- is
22 a type of fiber or a -- tremolite is a -- is
23 a substance or a entity that has been
24 identified as a specific morphology, I guess,
25 identified characteristics of a -- it has

1 identified characteristics.

2 There's -- within the
3 asbestos -- the asbestos literature
4 there's -- it's one of the forms -- forms of
5 asbestos that's described. For example, in
6 IARC, they describe all of the ones that have
7 carcinogenic properties. It's one of them.

8 Within the literature within
9 Johnson & Johnson's documents, there's
10 tremolite discussed as -- I assume them
11 referring to asbestos tremolite, asbestos in
12 a tremolite characteristic. I have seen
13 tremolite talc also mentioned in the
14 literature.

15 If you want a specific
16 discussion of each of those, again,
17 there's -- I understand there's experts that
18 are going to describe the distinguishing
19 characteristics of each of those.

20 I'm only setting out this is
21 what I have seen, talked about, in the
22 literature.

23 Q. So you are not an expert on the
24 differences between fibrous talc, asbestiform
25 talc, non-asbestiform talc and tremolite as

1 it relates to toxicity. Is that your opinion
2 today?

3 A. No, that's not what I'm saying.
4 I'm saying that if you want me to -- I'm --
5 if you want me to describe the
6 characteristics and the morphology of each of
7 those individually, that's something a
8 geologist would do.

9 But certainly as far as the
10 toxicity assessment I did, each of these
11 types of -- each of these words, I guess, or
12 names have been applied in the literature
13 when they talk about toxicity of talc. Some
14 of the literature talks about fibrous talc or
15 just -- other literature just talks about
16 talc. Some of it, for example, the IARC
17 monographs, distinguish between asbestiform
18 talc and non-asbestiform talc in their
19 assessments of the cancer risk.

20 And then tremolite is discussed
21 as a component of talc. And I have seen
22 papers that talk about tremolite --
23 nontremolite talc or tremolite-containing
24 talc. That's how you most often see it.

25 So it's the idea that it is a

1 constituent of certain mines that -- and
2 that's my understanding of it. But if you
3 want -- and they all -- they all certainly do
4 show that the toxicity can be affected,
5 whether it's a fiber or a platy particle. So
6 tremolite being a fiber would certainly
7 affect my overall assessment of risk. The
8 more tremolite that you would have would
9 make -- would make it more likely to be
10 reactive in terms of a foreign body response,
11 depending on the size.

12 Q. What's your basis for saying
13 that?

14 A. That's based on a fibrous form
15 versus a platy particle form. That's the
16 issue of -- I have that paragraph where I
17 talk about what macrophages look for, can
18 engulf or not engulf. So those are all
19 things that are important to a toxicologist
20 to understand exist.

21 But certainly within my
22 assessment I have to include literature from
23 all of those because of the fact that all of
24 those are relevant to the toxicity profile,
25 since I know that the cosmetic baby powders

1 and the data I've seen shows detection of
2 something called fibrous talc.

3 I see detection of tremolite
4 within certain samples of baby powder.

5 And then I have just the
6 general category of asbestiform versus
7 non-asbestiform when I consider the way, for
8 example, IARC has reviewed the
9 carcinogenicity.

10 So those are -- those are terms
11 that I'm laying out because I think they are
12 something you need to understand exists in
13 the literature.

14 Q. Okay. But I'm trying to
15 understand, not helping me understand the
16 literature. I'm trying to understand your
17 opinions with respect to toxicity.

18 Is it, for example, your
19 opinion that fibrous talc has the same toxic
20 potential -- let's focus specifically with
21 respect to ovarian cancer -- as tremolite?

22 A. I haven't formed that opinion,
23 but, again, I would -- my opinion has been
24 formed on the fact that we have complex
25 mixture that includes all of these things.

1 Q. Okay. And so when you're
2 looking at a complex mixture, you would agree
3 as a toxicologist it would be important to
4 understand the constituent elements of that
5 mixture, correct?

6 A. Yes, it is important to
7 understand that this is -- what is in the
8 mixture, and that's -- that's part of what I
9 try to do.

10 Q. Okay. And it would be
11 important before drawing conclusions from one
12 study that might have different constituent
13 components, it's important to understand the
14 relative toxicity of individual constituent
15 elements, correct?

16 A. Depends if you can or not. I
17 mean, there's certain types of studies you
18 can, where in the published literature that's
19 been described. That's why I'm pointing this
20 out. It's the idea that within the
21 literature, when you go through, it's
22 important to understand what you can say
23 about the consistency across the literature
24 where maybe different types of talc are
25 discussed.

1 And that's what I -- I think I
2 lay out for you. I tell you there's
3 consistency in certain toxic effects that are
4 seen. Regardless of the form that you're
5 looking at, talc has certain properties, and
6 all of these things are -- been shown to be
7 in the complex mixture, so I have -- as a
8 result, all of that literature has relevance
9 to at least the hazard part of my assessment,
10 and certainly have relevance to -- when you
11 want to talk about warning and the final risk
12 assessment, they're definitely relevant, but
13 certainly the -- when I go through this
14 process, I am trying to focus as much as I
15 can on a product that is most similar to the
16 one I'm assessing.

17 So obviously that's why --
18 that's one of the reasons I do look at the
19 human data, because the human data is
20 involving a consumer product use, which is
21 what I'm talking about here.

22 Q. Is it using specifically
23 Johnson's baby powder?

24 A. Many of them are, yes.

25 Q. Okay.

1 A. Based on my understanding of
2 what I see discussed within the literature.

3 Q. Did you identify in your report
4 specifically which report -- which studies
5 have used a consumer product manufactured by
6 Johnson & Johnson?

7 A. I haven't laid them out
8 individually, no, but I am aware of
9 discussions of this general issue within some
10 of the documents I've seen, and essentially
11 Johnson's body powders products were the
12 overwhelming share of the market.

13 Q. But you would agree that
14 studies that did not involve the consumer
15 product manufactured by Johnson & Johnson
16 should be given less weight when analyzing
17 whether or not there are risks associated
18 specifically with Johnson & Johnson's
19 products?

20 MS. PARFITT: Objection. Form.

21 MR. MEADOWS: Objection.

22 THE WITNESS: It depends on the
23 question being asked within the
24 assessment, the risk assessment. It
25 really does, I mean, because each of

1 these studies brings a piece of
2 evidence to the risk assessment.

3 And so the question is -- for
4 each one, you consider it on a
5 case-by-case basis. It is possible,
6 yes, that you would give less weight.
7 It's also possible that you would not,
8 dependent upon what you know about
9 that study and how it relates to other
10 studies that are out there.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. So methodologically, how would
13 I understand from your report marked as
14 Exhibit 4 under what circumstances to give a
15 study that relates to, for example,
16 industrial talc less weight than a study that
17 actually used Johnson's baby powder?

18 MR. MEADOWS: Objection.

19 THE WITNESS: Well, I've tried
20 to tell you that. That's what I said
21 for you. That's why I am doing it. I
22 certainly am trying to focus in on
23 studies that deal with the consumer
24 product.

25 But what I find when I look

1 across the studies that are dealing
2 with not the consumer product but
3 other descriptions, there is a
4 consistency in the types of effects
5 you see.

6 And since I'm not quantifying
7 the risk but identifying it as being
8 increased or not, in other words, is
9 it more likely than not that someone
10 exposed in this way could be at a risk
11 of ovarian cancer, that's what I'm
12 talking about.

13 So again, it's -- if I was
14 trying to identify differences in
15 cancer potency factors for different
16 types, then, yes, if I had an animal
17 study on each of those, I could
18 compare potency for cancer, but that
19 hasn't been done.

20 QUESTIONS BY MS. BRANSCOME:

21 Q. Okay.

22 A. So instead, what I have to do
23 is rely on what is available to me. And
24 based on my judgment, that's how I review the
25 studies.

1 Q. And so for the opinions that
2 you are offering in the MDL, you agree that
3 you are not quantifying the risk associated
4 with Johnson's baby powder, SHOWER TO SHOWER®
5 or Shimmer with respect to the potential for
6 causing ovarian cancer?

7 MS. PARFITT: Objection. Form.

8 THE WITNESS: In terms of a
9 cancer potency factor, that is true, I
10 am not. Instead, what I am doing is I
11 am quantifying whether or not I
12 believe that the risk is increased
13 above a background risk.

14 That has to do with -- that's
15 where I bring in, in my risk
16 assessment, the human data, because
17 the human data is showing
18 statistically significant increases in
19 risk in populations using the consumer
20 product.

21 So I have a quantification
22 where I'm using the word "increased,"
23 and I believe to a reasonable degree
24 of medical certainty that indeed the
25 risk is increased. So I'm quantifying

1 in that way, but I'm not giving it a
2 number. I'm not saying that the
3 cancer potency factor is such that you
4 increase the risk from one in a
5 million to 10 in a million to 1 in a
6 thousand. That I have not done
7 because I don't have the data, the
8 studies. The company has not done
9 studies on each of these to allow me
10 to do that.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. Okay. The reference that you
13 made to the human data that you believe shows
14 a statistically increased risk in populations
15 using the consumer product, have -- which --
16 have you identified in your report which of
17 those studies are specifically using a
18 product that was manufactured by Johnson &
19 Johnson?

20 A. I don't lay that out for my
21 report, I do not, but certainly it is
22 something that for some of the studies I
23 believe you can -- you might be able to get
24 some of that information from. But certainly
25 I have not laid that out individually in my

1 report, no.

2 Q. And you would agree that for
3 some of those studies there is no information
4 as to the specific type of consumer talc that
5 the individuals who are being studied used,
6 correct?

7 MS. PARFITT: Objection. Form.

8 THE WITNESS: I would agree
9 that in some of those studies they're
10 not saying, but that is why you look
11 at the evidence overall.

12 And what's important to look at
13 in terms of now -- if you wanted to go
14 to Bradford Hill, that's why you look
15 at things such as consistency. So
16 what do the studies show. We see a
17 certain level of increased risk across
18 studies, regardless of who did the
19 study or what population was being
20 looked at.

21 So that's the best way I can
22 answer that for you. That is -- that
23 is part of the -- of the assessment
24 that you look at.

25

1 QUESTIONS BY MS. BRANSCOME:

2 Q. In reaching your opinion in the
3 MDL that there is an increased risk above
4 background of ovarian cancer from the use of
5 products manufactured by Johnson & Johnson,
6 have you made an attempt to identify
7 specifically which studies, the human studies
8 on which you rely, test or look at people who
9 have used Johnson & Johnson's products?

10 MS. PARFITT: Objection. Form.

11 THE WITNESS: It's my -- my
12 review of the study indicates that I
13 would say for the vast majority of
14 them you cannot do that.

15 But you can take what is
16 reported and look at things such as
17 market share and those kind of things
18 to get an idea of what you believe the
19 exposure would have been.

20 But certainly I have not -- I
21 have not tried to apply some kind of a
22 numerical value to how many people in
23 the study may have used Johnson's baby
24 powder or not, no, that has not been
25 done. I don't think anybody -- any of

1 the bodies that have looked at this
2 have done that.

3 QUESTIONS BY MS. BRANSCOME:

4 Q. You have not done a market
5 share analysis, correct?

6 A. No, I've seen this in documents
7 only. I have not done my own. There are
8 company documents that talk about their
9 market share.

10 Q. Okay. Have you made an attempt
11 to examine the levels of fibrous talc or
12 asbestiform talc that are in different
13 consumer products, aside from Johnson's baby
14 powder or SHOWER TO SHOWER® or Shimmer?

15 A. So for that are you referring
16 to things such as -- other types of cosmetics
17 like foundations or lipsticks or --

18 Q. I'll rephrase.
19 Have you made any attempt to
20 examine whether other cosmetic talc body
21 powders have a different percentage of
22 fibrous, or what you refer to as asbestiform
23 talc, from the Johnson & Johnson products?

24 Have you done any analysis to
25 make that comparison one way or the other?

1 MS. PARFITT: Objection. Form.

2 THE WITNESS: I certainly
3 haven't done -- I certainly didn't do
4 a directed analysis to try to
5 determine that, but there is
6 information, I believe, in -- I think
7 if you look at some of Dr. Longo's
8 work, that may be there.

9 And I believe in Dr. Blount's
10 published paper there may be a
11 discussion of the type of powder
12 product used, where she was looking
13 for -- at least for asbestiform --
14 asbestos within the talc. It may be
15 tremolite as well, but -- if you want
16 me to look, I can do that. I just
17 don't recall whether -- I think she
18 did talk about sources of the talc,
19 where it came from, so...

20 QUESTIONS BY MS. BRANSCOME:

21 Q. Okay. But as you sit here
22 today, you can't point me to any analysis
23 that you did or an analysis that you relied
24 on that would relate different brands of
25 cosmetic talc body powders with respect to

1 their constituent components?

2 MS. PARFITT: Objection.

3 Completely misstates her testimony.

4 She mentioned Dr. Blount. She

5 mentioned others.

6 THE WITNESS: So I think what I
7 started with, I said I haven't done a
8 directed analysis to try to determine
9 specifically how this product versus
10 this product versus this product may
11 have looked over time, because I don't
12 have access to a full data to do that.

13 But what I do have is data that
14 has -- I do see published data, for
15 example, Blount and maybe some of the
16 other published studies, that looked
17 at this issue, at least of asbestos
18 presence in talc. And I believe
19 Dr. Longo also had things that weren't
20 just Johnson's. I believe he had
21 Cashmere Bouquet, for example, samples
22 in some of the things he looked at.

23 So I can point you to those
24 things that I have reviewed, but I
25 haven't -- there's nowhere in here

1 that I state for you that it's my
2 opinion that Cashmere Bouquet has this
3 specific pattern of constituents as
4 compared to Johnson & Johnson's. No,
5 I have not done that.

6 QUESTIONS BY MS. BRANSCOME:

7 Q. Okay. And that would be true
8 for any other brand of cosmetic talc, body
9 powders, Jean Nate, Lily of the Valley, not
10 just Cashmere Bouquet, correct?

11 MS. PARFITT: Objection.

12 THE WITNESS: That is correct,
13 I don't have access to that
14 information.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. Have you done any analysis of
17 the constituent components of talc and how
18 they have changed even within Johnson's --
19 Johnson & Johnson's manufactured products,
20 how the constituents of the consumer products
21 may or may not have changed over time?

22 A. I've done some of that, yes,
23 and I laid that out, I think, for you, when I
24 talk about the differences in the products
25 that are described within the documents, the

1 company documents, from the '70s versus the
2 '80s versus later on, as far as the changes
3 that were made to specifications of the
4 product, for example. That's something --
5 and I think I've talked about that a bit at
6 trial as well.

7 Q. Okay. And is it your view that
8 the risk potential for Johnson & Johnson's
9 manufactured products have changed at all
10 over time with respect to ovarian cancer?

11 MS. PARFITT: Objection.

12 THE WITNESS: I have not -- I
13 have not attempted to differentiate a
14 risk potential at only one point in
15 time.

16 What I have done over points of
17 time is looked at the issue of
18 warnings and what should be warned
19 about.

20 But my analysis related to the
21 hazard or the risk assessment of the
22 products is considering all of the
23 available information, which would be
24 all of that information over time.

25

1 QUESTIONS BY MS. BRANSCOME:

2 Q. Okay. You talk about, in
3 paragraph 35 primarily -- we'll talk about
4 the fragrance components in more detail, but
5 you talk about the idea of chemicals being a
6 potential irritant.

7 Are you familiar with that?

8 A. Yes, that's correct.

9 Q. Is it your position that any
10 product that contains chemicals that could be
11 an irritant should be labeled with a health
12 warning?

13 MS. PARFITT: Objection.

14 MR. MEADOWS: Okay.

15 THE WITNESS: I don't think
16 that's -- no, I don't think I've
17 formed that specific opinion.

18 But the opinion that I think
19 I'm expressing here is that when you
20 have a -- the information that I have,
21 which unfortunately the company hasn't
22 given us percentages or actual levels,
23 instead, what I do as a toxicologist,
24 I look at what is there. And when I
25 see over a hundred chemicals there,

1 that 70 percent of them have been
2 linked as an irritant hazard, there is
3 the issue of toxicological additivity
4 to consider.

5 So certainly as a risk
6 assessor, when I have that many
7 potential sources of irritation as far
8 as chemicals going into a complex
9 mixture, certainly I think I have
10 formed the opinion that I think that
11 is something that needs to be
12 considered when you're talking about
13 providing information to consumers,
14 yes.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. As a toxicologist, would it be
17 important to you to understand the exact
18 percentages of all of the constituent
19 components of, say, Johnson's baby powder,
20 for example?

21 A. Are you talking about just the
22 fragrance or are you talking about everything
23 that's in it?

24 Q. Dr. Plunkett, you referenced
25 the fact that the company has not provided

1 you with specific percentages, and so I'm
2 asking you, is that something that as a
3 toxicologist would be important information
4 to you?

5 A. Depends. Certainly with the
6 fragrance -- and I'm talking about the
7 conversation about this paragraph is focusing
8 on the fragrance components.

9 So, yes, I mention that it
10 would be nice to know, it would be good to
11 know, if we could, exactly what was in there,
12 because I could quantify the hazard or
13 quantify the risk, actually. So instead, I
14 have -- I identify it as a hazard, but I
15 can't quantify it without those levels.

16 But does that change -- make a
17 difference in the overall conclusions I draw?
18 No, it doesn't affect the overall conclusions
19 that I have drawn, but it adds that other
20 piece of the puzzle that deals with the fact
21 that we have a complex mixture that have a
22 combination of ingredients that target
23 irritation.

24 And irritation and the
25 potential to produce an inflammatory

1 response, in my -- if you've read my report,
2 you understand that I think that's a key
3 factor in increasing the risk for ovarian
4 cancer.

5 Q. Understanding the percentages
6 of the constituent components, is that
7 limited only to fragrance, or would it also
8 be important to understand the percentages
9 for the heavy metals that you contend are in
10 Johnson's baby powder?

11 A. So if I was trying to define
12 the hazard of each component, I would
13 certainly want one to know that. As a
14 result, what I'm doing instead is looking at
15 the complex mixture. In other words, this is
16 a mixture of all these things.

17 I break out those individual
18 components, or constituents, to tell you
19 about the hazard that is brought to play or
20 the toxicity profiles that exists. And
21 what's important about that in my overall
22 evaluation of the end product, which is what
23 my risk assessment is based on, the end
24 product, shows that I have multiple
25 components with similar types of effects.

1 And as a toxicologist, when you do that, that
2 affects the conclusion that you can draw
3 about a body of literature.

4 Q. Okay. You do understand that
5 there is testing data available about the
6 percentages of the constituent components
7 with respect to heavy metals, et cetera, that
8 have been in Johnson's baby powder over time,
9 correct?

10 A. There is some information.
11 Unfortunately, the information is not
12 complete as to every lot or every sample, as
13 far as what I have seen. And also, there's
14 some -- some of the sampling is reported as
15 more of a limit versus an actual
16 quantification. So it depends upon which --
17 which result, study result or document,
18 you're looking at.

19 There is some there, yes, and
20 that's one of the reasons why I identified
21 these as part of my risk assessment, because
22 I look for a pattern of these metals that are
23 known to carry a hazard and whether or not
24 these are ones I'm seeing detected time and
25 time again.

1 Q. But you made no attempt to
2 quantify the risk with respect to any of
3 those components or use that data in any way,
4 correct?

5 MS. PARFITT: Objection. Form.

6 THE WITNESS: No, I used
7 that -- that data as part of -- my
8 risk assessment as part of my hazard
9 assessment, absolutely. It's part of
10 the hazard assessment.

11 But as far as quantifying them
12 individually, no. I am quantifying
13 the risk and looking at the risk of
14 the entire product, not of just one
15 individual component of the product.

16 QUESTIONS BY MS. BRANSCOME:

17 Q. Well, we already discussed
18 you're not quantifying the risk with respect
19 to the entire product, correct?

20 A. Well, I'm quantifying it in
21 terms of an increase above background, which
22 I'm not giving you a -- I told you I wasn't
23 giving you a cancer potency factor. That is
24 true. That I am not doing.

25 But I am quantifying it by

1 using a word such as an increase -- an
2 increased risk.

3 Is that a specific number? Am
4 I telling you that it's increased by two
5 times or four times or six times? No. The
6 data available did not allow us to do that,
7 with the exception of the epidemiological
8 data. And the epidemiological data can show
9 you that in that piece of evidence there
10 appears to be a 30 percent increased risk
11 above background.

12 Q. Did you make an attempt to
13 quantify the risk with the data that you had
14 available to you with respect to the final
15 consumer product?

16 A. I could not, based on the data
17 I had, because I didn't have a
18 well-controlled animal study to be able to
19 pull that out that way.

20 Instead, what I -- in this type
21 of weight of the evidence, you look at what
22 you might be able to quantify based on the
23 human data. And certainly the human data
24 showing the statistically significant
25 consistent findings across studies for that

1 30 percent increased risk, that is part of my
2 overall weight of the evidence for me making
3 the statement the risk is increased.

4 But you'll notice I don't say
5 increased risk of 30 percent, because I don't
6 believe that I can state that with certainty
7 in the way I do a risk assessment. But
8 certainly as any one individual -- any one
9 individual piece of evidence or any one body,
10 like the epi data, others have made -- other
11 bodies who have looked at the -- talked about
12 the consistency of the increased risk signal
13 in the epi studies as being in the range of
14 30 percent.

15 Q. Okay. But you would agree that
16 based on the methodology that you applied in
17 this case, you could not say to a reasonable
18 degree of scientific certainty that there is
19 an increased risk of, for example, 30 percent
20 with respect to use of Johnson's baby powder
21 and ovarian cancer, correct?

22 MR. MEADOWS: Objection.

23 THE WITNESS: I have not done
24 that. And I'm not saying that
25 somebody else couldn't do that. I

1 have not -- I have not chosen to do
2 that based on my evaluation of the
3 data.

4 QUESTIONS BY MS. BRANSCOME:

5 Q. And the same would be true if I
6 asked that question and substituted any
7 particular number, a 10 percent increased
8 risk, a 20 percent increased risk, correct?

9 MR. MEADOWS: Objection.

10 THE WITNESS: I haven't given a
11 specific number in my final opinions,
12 that is true.

13 QUESTIONS BY MS. BRANSCOME:

14 Q. Okay.

15 A. I've tried to explain to you
16 what evidence I do think is there, however.

17 Q. Now, we've talked about
18 different types of talc that might have
19 different constituent components, but you
20 also look at exposure to talc in an
21 occupational setting.

22 Do you recall that?

23 A. Some of the studies that I've
24 relied upon, yes, some of them were
25 occupational.

1 Q. Okay. And you understand that
2 in an occupational setting, you would agree
3 that the exposure, particularly via
4 inhalation, would be much higher than it
5 would be through the use of a consumer
6 product, correct?

7 A. It depends on the occupation,
8 but, yes. For example, I would agree a miner
9 would be expected to have that, but there are
10 certain, quote/unquote, occupational studies
11 where the exposure levels that -- for
12 example, there are -- I believe there's at
13 least one study that looked at application of
14 talc powders in -- maybe in a material,
15 coating materials in a factory. Those kinds
16 of studies would be different than a mining
17 study.

18 But, certainly, yes, I
19 understand that occupational studies, the
20 inhalation exposure is the pathway that would
21 be predominant versus in the consumer body
22 powder use, I'm talking about the predominant
23 exposure pathway in my opinion is going to be
24 through perineal use, even though inhalation
25 exposure can occur.

1 Q. Is it your opinion as you sit
2 here today that someone could develop ovarian
3 cancer through -- exclusively through the
4 inhalation of Johnson's baby powder?

5 MS. PARFITT: Objection.

6 THE WITNESS: I haven't formed
7 that opinion at this point in time.

8 QUESTIONS BY MS. BRANSCOME:

9 Q. Have you done any analysis or
10 can you point me to any analysis in your
11 report that makes a comparison of the
12 exposure levels that might be seen in an
13 occupational setting to what would be seen by
14 a consumer?

15 A. Are you asking me for a piece
16 of evidence that does that comparison, or is
17 there evidence that allows you to do that
18 comparison?

19 Q. Have you cited or discussed any
20 of the evidence or done an analysis in any
21 way that would compare exposure levels in an
22 occupational setting to what you would
23 anticipate a consumer using Johnson's baby
24 powder might be exposed to?

25 A. I don't think I did it as a

1 separate analysis, but as part of my analysis
2 I considered evidence that showed -- provided
3 me with such data. So, for example, if you
4 want, I can point you to a -- I have an
5 inhalation paragraph, I think.

6 Let me look for it real quick.
7 See if I can find it quickly for you. I
8 don't want to waste your time.

9 Q. Sure.

10 A. So there's -- I don't see it
11 cited here, but there's at least one document
12 I reviewed where the company themselves made
13 a comparison, and I have seen that, of
14 inhalation exposure to talc suspended in air
15 with diapering. Dr. Longo has done a
16 measurement of exposure in air with perineal
17 application of talc. So I'm aware of those
18 studies.

19 And then I certainly am aware
20 of the fact that those numbers are different,
21 or smaller, than many of the numbers I see
22 reported in some of the occupational studies.
23 But I can't say that's true for all.

24 I would certainly, though, say
25 that if you're just talking inhalation, I

1 certainly would expect a miner or a miller to
2 have a greater potential for inhalation
3 exposure than routine use of the consumer
4 product, with the exception of the studies --
5 the reports of large amounts of exposure in
6 children where the inhalation -- where they
7 were inhaling large amounts of powder.

8 And so that's a different
9 story. That's sort of an acute overdose
10 exposure, I guess, versus the typical daily
11 exposure through occupational or consumer
12 use.

13 Q. And that raises an interesting
14 question. You discuss health hazards
15 associated with talc being known, and in some
16 cases deaths had been reported.

17 You're aware that those relate
18 to asphyxiation deaths, correct?

19 A. Or long-term injury to lungs.
20 Maybe not an immediate asphyxiation, but lung
21 damage produced by large amounts -- some of
22 the children would go to the hospital and be
23 sick for a while and then die. So they
24 didn't asphyxiate immediately, right? But
25 some of them did. You're exactly right.

1 Both of those things occur, and
2 I address that also in my warning section
3 about the fact that that warning didn't --
4 was not put on the product for a long period
5 of time even though those types of reports
6 were coming in early.

7 Q. You would agree that that is a
8 completely different biologic mechanism than
9 what you are proposing the biological
10 mechanism is for ovarian cancer to develop
11 with respect to talc use, correct?

12 MR. MEADOWS: Objection.

13 THE WITNESS: I would agree
14 that it's an acute response versus
15 chronic, yes, that I agree with.

16 It's not entirely different in
17 some cases because some of the tissue
18 reactions you saw were indicative of
19 irritation when some of the lung
20 samples were looked at. But
21 certainly, yes, that's acute exposure
22 versus chronic exposure, and I'm
23 focusing on ovarian cancer on chronic
24 exposure scenarios.

25

1 QUESTIONS BY MS. BRANSCOME:

2 Q. Okay. Now, you would agree
3 that -- so let's set aside inhalation.

4 You agree that for talc -- for
5 Johnson's baby powder or another one of
6 Johnson & Johnson's consumer talc products to
7 reach an individual's ovaries, it must pass
8 from the perineum, through the vagina and the
9 cervical canal, move across the uterus -- and
10 again, it's the ciliary motion of the
11 fallopian tubes -- cross the peritoneal space
12 between the fimbriae and ovaries, escape
13 phagocytosis in the peritoneal space, and
14 then attach to the surface of the ovaries,
15 correct?

16 MS. PARFITT: Objection. Form.

17 MR. MEADOWS: Okay.

18 THE WITNESS: If the issue is
19 attaching to the surface, yes.
20 There's also some information
21 indicates the site of attack may be
22 actually at the fallopian tube exit to
23 the peritoneum. But, yes, that's
24 correct, there's been some discussion
25 in the literature on ovarian cancer

1 about whether the tumors are arising
2 in the tubes versus the ovaries.

3 But I would agree, I think
4 both -- I think both of those
5 things -- those things -- there is a
6 passage that has to happen, regardless
7 of whether the end point is at the
8 fallopian tube or at the ovary.

9 QUESTIONS BY MS. BRANSCOME:

10 Q. Okay. Is it your view that the
11 consensus has been reached that ovarian
12 cancer can be caused by talc landing in the
13 fallopian tubes?

14 A. I haven't formed that opinion,
15 though I do believe this will be discussed by
16 some of the other experts.

17 Q. Okay. Have you personally
18 conducted any tests or experiments to confirm
19 the theory that talc migrates from
20 application at the perineum to the ovaries?

21 A. If by that you mean something
22 where I performed a laboratory test myself,
23 no, I have not done that.

24 Q. As a toxicologist, are you
25 capable of doing that?

1 A. Yes, I believe if asked I
2 could -- I could attempt to design something
3 to look at that issue.

4 Q. Okay.

5 A. But I would argue that I think
6 it doesn't make a lot of sense to revisit
7 based upon what we already know from the
8 scientific literature and the review papers
9 from the gynecological community. I believe
10 it's -- it's understood that it can migrate.

11 Q. In your opinion, has an animal
12 model been successfully developed that would
13 allow the testing of talc migration in humans
14 from the perineum to the ovaries?

15 A. I think I tell that you in my
16 report. I believe that the human data is the
17 relevant data to look at this issue.

18 So it would be very difficult
19 to design a study to do this based on the
20 typical laboratory species that are used in
21 toxicology testing. Even -- even the monkeys
22 have issues, and the biggest issues with
23 monkeys is the ethicality of using a monkey
24 to settle -- to address a question that I
25 believe is settled within the gynecological

1 and scientific community.

2 Q. Now, you state in your report
3 that talc that's applied through perineal
4 use -- I believe the term you use --
5 routinely migrates to the ovaries.

6 Is that your opinion?

7 A. Are you reading from my report?

8 MR. MEADOWS: To the extent
9 that question is still lingering, I
10 object to it.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. On paragraph 43 on page 29.

13 A. So I think as I've stated it,
14 the studies that I have reviewed demonstrate
15 that inert particles routinely move from the
16 lower female reproductive tract up into
17 fallopian tubes and towards the ovaries.

18 Q. What do you mean by routinely?

19 A. It's the percentages of
20 movement that are reported in the patients.
21 In other words, if you look at some of the
22 individual studies -- if you want we can pull
23 them out, but, you know, eight of ten
24 patients, nine of ten patients, all the
25 patients showed movement of the particles.

1 And then on top of that, you
2 have the review articles that talk about
3 migration of particles in the female
4 reproductive tract and are describing it as
5 an event that is known to occur. So it's
6 those things weighed together.

7 But certainly routine could be
8 supported by the observations where the
9 majority of the patients in the studies were
10 showing movement of inert particles.

11 Q. Is it your opinion that every
12 perineal application of cosmetic talc powder
13 results in talc being deposited on the
14 ovaries?

15 A. I have not formed that opinion,
16 no.

17 Q. Have you formed an opinion as
18 to with what frequency -- so let's say
19 someone uses a cosmetic talc on a perineal
20 application ten times. Out of those ten
21 times, have you formed an opinion as to how
22 many of those instances would talc deposit on
23 the ovaries?

24 MS. PARFITT: Objection.

25 THE WITNESS: I haven't formed

1 an opinion in that particular way, no.
2 I think what I've -- I've tried to
3 describe to you in my report is that I
4 believe it is known that inert
5 particles have the ability to migrate.
6 And based on that, I form the opinion
7 that it's my opinion to a reasonable
8 degree of scientific certainty, which
9 would be a more likely than not
10 standard, that particles of talc would
11 be migrating when women are using them
12 perineally. But I haven't told you
13 that it has to be a specific number,
14 no.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. Have you done any analysis to
17 establish over a lifetime use of cosmetic
18 talc where the app -- the perineal
19 application, with what frequency during a
20 lifetime the talc may have been deposited on
21 that individual's ovaries?

22 A. So I certainly looked for
23 information to allow me to assess that, but
24 unfortunately those kinds of studies would be
25 unethical to do. Because that would be a

1 matter of sampling women during -- using them
2 and then taking biopsies, and that's
3 something that would be difficult to do. I
4 would say impossible to get approval to do
5 under human testing guidelines.

6 Q. Okay. So it's your opinion
7 that it is possible for talc that is applied
8 through a perineal application to reach the
9 ovaries, but you cannot say with what
10 frequency that occurs?

11 MS. PARFITT: Objection. Form.
12 Misstates her testimony.

13 THE WITNESS: That's not --
14 what I'm telling you is, I think it --
15 that to a reasonable degree of
16 scientific certainty that it migrates,
17 and that would be the standard of more
18 likely than not. I think it's more
19 likely than not that the talc is
20 reaching the ovaries when people are
21 using it perineally.

22 I did form the opinion -- and
23 I've talked about this at trial and
24 yesterday. I have formed the opinion
25 that this is a issue of chronic or --

1 or use of the products. In other
2 words, people aren't just using it
3 once, but people are using it -- you
4 can use the word "routinely," as a
5 habit, in their daily life perineally.
6 And that would be consistent with the
7 studies that have been done that have
8 looked at the issue of dose response.

9 And I discuss that in my
10 report, too.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. Okay. But you have not made an
13 attempt to quantify, nor have you seen it in
14 the literature, the overall dose of talc that
15 someone might be exposed to in terms of
16 contact with the ovaries throughout their
17 lifetime, chronic use of cosmetic talc?

18 MS. PARFITT: Objection. Form.

19 THE WITNESS: Those -- that's
20 the kinds of studies that have not
21 been done and I believe could not be
22 done based upon ethics of human
23 testing. But certainly I -- that --
24 that data is not available that I'm
25 aware of.

1 MS. BRANSCOME: Okay. Can we
2 just go off the record for a second?

3 VIDEOGRAPHER: We are going off
4 the record at 12:23 p.m.

5 (Off the record at 12:23 p.m.)

6 VIDEOGRAPHER: We are back on
7 the record at 12:24 p.m.

8 QUESTIONS BY MS. BRANSCOME:

9 Q. As you sit here today, how
10 would you characterize the biological
11 mechanism by which you claim Johnson's baby
12 powder, their other cosmetic talc products,
13 present a risk of ovarian cancer?

14 A. So I outline this for you in
15 the MDL report. I think I have a section
16 on -- let's see if I can -- you want me to
17 tell you where or...

18 So paragraph 65, I think I set
19 out part of this argument or part of this.
20 And then also in paragraph -- I believe in
21 67.

22 Q. All right. Well, let me take a
23 step back.

24 Is it your opinion that the
25 biological mechanism by which talc, cosmetic

1 talc, can in your view cause ovarian cancer,
2 is that something that has been definitively
3 established?

4 A. What do you mean by
5 definitively? I mean, I think -- I believe
6 more likely than not that -- so I believe I
7 have reached a conclusion that I think what
8 the most likely biologically plausible
9 mechanism, but maybe you're ask -- meaning
10 something else.

11 Q. Okay. Well, let's start with
12 specifically you discuss a number of
13 different potential mechanisms in your
14 report. So if you believe you have reached
15 an opinion more likely than not about the
16 specific biological mechanism by which
17 cosmetic talc and specifically Johnson &
18 Johnson's products can cause ovarian cancer,
19 can you describe that for me?

20 A. So it's a chronic inflammatory
21 process, and so -- but like all compounds,
22 constituents, even drugs that we look at, we
23 don't know each individual step within the
24 molecular mechanism.

25 Instead, what we know is that

1 there are certain components to the process
2 of cancer that are consistent with the
3 effects produced by talc, and we know that
4 talc can produce a chronic inflammatory
5 process.

6 And so that's why I was
7 pointing you to the paragraph 65 and I think
8 67.

9 Q. Is it your opinion that
10 consensus has been reached in the scientific
11 community that cosmetic talc can cause
12 ovarian cancer through a chronic inflammatory
13 response?

14 MS. PARFITT: Objection.

15 THE WITNESS: I don't know that
16 that's exactly the opinion I've
17 formed.

18 Would you like me to -- I could
19 restate what I believe, but I don't
20 think that's exactly how I would state
21 it, no.

22 QUESTIONS BY MS. BRANSCOME:

23 Q. Okay. So then yes or no: Has
24 consensus been reached in the scientific
25 community that cosmetic talc can cause

1 ovarian cancer through a chronic inflammatory
2 process?

3 A. I don't believe I formed the
4 opinion either way, that it's yes or no,
5 because I haven't tried to -- I haven't tried
6 to form the opinion about what the -- in
7 other words, I haven't -- I can't say for
8 every scientist out there.

9 I certainly can tell you what I
10 believe based on what the consensus of
11 science says about mechanisms underlying
12 cancer and the consistency of those
13 mechanisms with talc, and then I have an
14 opinion about what I believe that information
15 says.

16 I do believe my opinions,
17 however, are consistent with some consensus
18 statements, such as the issue on the
19 mechanism is consistent with consensus
20 opinion reached by IARC, where they discuss
21 the inflammatory process as an underlying
22 biologically plausible mechanism that can
23 lead to ovarian cancer.

24 I think it's consistent with
25 the Canadian risk assessment where they

1 discuss those issues.

2 I think it's consistent with --
3 I don't know if the ACOG statement goes that
4 far on mechanism, but it does talk about
5 ovarian cancer. That's a recent statement.

6 And I believe it's consistent
7 with some of the -- I believe my opinions are
8 consistent with some of the opinions reached
9 by others in science, but that's the only way
10 I can answer that for you.

11 Q. Okay. Because you have not,
12 one way or the other, done an evaluation of
13 whether or not chronic inflammatory process
14 is a biological mechanism on which the
15 scientific community has reached general
16 consensus with respect to the causation of
17 ovarian cancer; is that correct?

18 MR. MEADOWS: Objection.

19 THE WITNESS: I can't tell you
20 that -- I can't tell you that every
21 body that's looked at it, but I have
22 tried to point you to evidence that I
23 believe is consistent with that.

24 For example, the IARC would be
25 a good example of consensus on

1 biologic mechanism because they have a
2 whole part of their assessment of
3 non-asbestiform talc and perineal
4 cancer -- of perineal use and ovarian
5 cancer that discusses mechanism. And
6 that is consistent with what I have
7 said. So there is a consensus
8 opinion.

9 But I guess what I'm saying to
10 you is I can't tell you that all --
11 all people who have put statements
12 have come to that exact opinion. But
13 there aren't that many places out
14 there that are addressing that issue
15 as far as the consensus on a
16 mechanism. There's more statements
17 about the relationship between ovarian
18 cancer and talc use than there are
19 drilling down to what the mechanism
20 must be.

21 QUESTIONS BY MS. BRANSCOME:

22 Q. Okay.

23 A. So that's the issue. It's a
24 little -- it's a little hard to answer that
25 yes or no because of that.

1 Q. Okay. When we talk about the
2 idea of biologic -- a biologically plausible
3 mechanism, what is your understanding of the
4 term "plausible" in that expression?

5 A. When I use the word
6 "biologically plausible mechanism" or
7 "biologic plausibility," I'm using it
8 consistent with what Bradford Hill uses,
9 that's it's the idea that the evidence that
10 available makes -- the evidence that
11 available supports a pathway where you can go
12 to exposure to response.

13 So in other words, there's a --
14 the biological information is consistent with
15 how we know cancer can develop. That's the
16 response we're looking at. And the exposure
17 we're looking at is known to produce those
18 kind of biologic events.

19 So as a result, based upon
20 knowing that there's a consistency between
21 the data that we have on the -- on the
22 exposure and the data that we have on the way
23 cancer can occur, those things -- those
24 things align. So that makes it biologically
25 plausible that that could occur.

1 Q. But you would agree that
2 biological plausibility suggests that it is a
3 plausible explanation, but it may not have
4 been established as the definitive pathway by
5 which a disease is caused, correct?

6 MS. PARFITT: Objection. Form.

7 THE WITNESS: Well, I would
8 agree that in the discussion of
9 biologic plausibility in the Bradford
10 Hill paper that is true. But if you
11 look at people's discussion of the use
12 of -- I want to say "biological
13 mechanism" rather than the word
14 "biologic plausibility," because
15 really as a toxicologist I'm trying to
16 understand whether there's a biologic
17 mechanism that makes sense. Those are
18 words I like to use. Does it make
19 sense that this exposure could lead to
20 this response.

21 And that involved looking at
22 the mechanistic data or the data on
23 the way toxic responses are produced
24 by talc, and whether or not they align
25 with the types of toxic insults that

1 are known to be able to produce,
2 specifically, ovarian cancer.

3 QUESTIONS BY MS. BRANSCOME:

4 Q. Is it your opinion that IARC,
5 for example, has concluded that the
6 biological mechanism by which talc may cause
7 ovarian cancer is chronic inflammation?

8 MS. PARFITT: Objection.

9 THE WITNESS: I don't know that
10 they have used -- they've described it
11 quite that way, but they do describe
12 what they believe is the biologically
13 plausible mechanism. Because they do
14 organize and use within the
15 definitions of how they describe some
16 things that are consistent with what
17 Bradford Hill uses.

18 QUESTIONS BY MS. BRANSCOME:

19 Q. Okay. And obviously you're
20 familiar with the IARC evaluation of talc
21 with respect to the possibility of causing
22 ovarian cancer, correct?

23 A. Yeah. If you mean the recent
24 one, yes, the most recent assessment.

25 Q. Yes.

1 And that IARC has in fact
2 classified cosmetic talc not containing
3 asbestos as possibly carcinogenic to humans,
4 correct?

5 A. It's a possible human
6 carcinogen 2B, that's correct.

7 Q. Okay. And if a product is
8 listed in the 2B category, does that
9 necessarily mean the product, in your view,
10 is carcinogenic?

11 A. Not always, because that comes
12 down to an assessment of -- then you're
13 putting together a -- a risk assessment that
14 looks at -- looks at -- across the
15 information that you have available. And
16 that may be that -- that the -- the possible
17 is all you can say, or it may be that you
18 believe that the information -- there's
19 enough information there to take it further.

20 Has a possibility -- that's
21 what I said, they do a hazard assessment.
22 They rank things on hazard based on -- on
23 unlikely -- not enough evidence, less -- the
24 possibility, the probability or it's known.

25 Q. In your opinion, is your

1 characterization of the risk of Johnson's
2 baby powder or talcum powder products with
3 respect to ovarian cancer, are you in the MDL
4 characterizing that risk as a higher level of
5 risk than what IARC characterized it, or do
6 you agree with the 2B characterization of
7 possibly carcinogenic?

8 MS. PARFITT: Objection. Form.

9 THE WITNESS: So I'm not IARC,
10 so I don't try to second-guess there.
11 They have reached a conclusion, and I
12 use that as part of my weight of the
13 evidence. So I haven't formed the
14 opinion they're right or wrong.

15 But I have done a different
16 assessment. My assessment, first off,
17 includes more information than IARC
18 had, so as a result, I have formed the
19 conclusion that I believe that it's
20 more likely than not that exposure
21 to -- perineal exposure to talc body
22 powders increases the risk of ovarian
23 cancer in women who use that product.

24 And I will put the caveat this
25 has to be chronic use or repeated use,

1 because I've gone -- I've said that
2 many times.

3 So that -- that is my opinion.
4 So that's a different statement and a
5 different assessment than what IARC
6 does.

7 But -- so I don't disagree with
8 their possible -- I weigh that, but I
9 believe the evidence for the risk
10 assessment shows me that it's more
11 likely than not that this -- this
12 exposure will increase the risk above
13 a background risk for women who are
14 using this product.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. And how do you define chronic
17 or repeated use?

18 A. Well, that is variable within
19 the literature. For me, chronic is
20 exposure -- if as a toxicologist, I would
21 typically say chronic use is years of use.
22 It doesn't have to be daily, but it would be
23 years. That's the most common description
24 you see in toxicology, so I would say that's
25 fair. That's a fair assessment of my

1 opinion.

2 Q. Is there a threshold of the use
3 of Johnson & Johnson's talcum powder products
4 below which there is no increased risk, in
5 your opinion, of ovarian cancer?

6 A. We have not identified that
7 threshold. That's what's missing within
8 the -- the literature that exists today. So
9 I can't tell you whether or not with only a
10 thousand applications over a lifetime that
11 is -- is not enough for every individual or
12 not, but certainly I do believe that the --
13 that the exposure has to be habit, routine,
14 chronic, something that is done maybe not on
15 a daily basis but on a routine basis in a
16 woman's life.

17 So that is consistent, I think,
18 with the literature.

19 MS. BRANSCOME: Okay. We can
20 go off the record.

21 VIDEOGRAPHER: We are going off
22 the record at 12:36 p.m.
23 (Off the record at 12:36 p.m.)

24 VIDEOGRAPHER: We are back on
25 the record at 1:35 p.m.

1 QUESTIONS BY MS. BRANSCOME:

2 Q. Good afternoon again,
3 Dr. Plunkett.

4 A. Good afternoon.

5 Q. I want to talk a little bit
6 about the Health Canada assessment.

7 We talked about this before,
8 but this is something that you reviewed after
9 you completed your report which has been
10 marked as Exhibit 4, correct?

11 A. Yes, and I wanted to tell you,
12 I did not bring all those documents printed.
13 I apologize. So there is a separate Health
14 Canada draft risk assessment that I didn't
15 print.

16 Q. Okay. So when you're referring
17 to the Health Canada analysis, what document
18 are you specifically referring to?

19 A. So I'm referring to the -- the
20 combined documents, but there are times when
21 you've asked me questions that I've been
22 referring -- and I tried to say, I believe,
23 Taher.

24 But, yes, some of the questions
25 you asked me when I said Health Canada, I was

1 talking about the combined documents, which
2 would include their -- I guess it's called a
3 draft risk assessment document, yeah, which
4 refers to this document but is a separate --
5 is their own separate statement.

6 Q. As you sit here today, what is
7 your understanding of the current position
8 that has been articulated in the collection
9 of documents that you refer to as Health
10 Canada with respect to any potential
11 relationship between cosmetic talc and
12 ovarian cancer?

13 A. So that's why I did print out
14 the small one, because I think it summarized
15 it. So here, if you look at this Exhibit 6,
16 it makes specific conclusions or draws --
17 makes statements. And essentially it talks
18 about talc being a possible risk of ovarian
19 cancer, but then it gives women specific
20 advice about what to do in order to minimize
21 exposure to the products, and some of that
22 was relevant as well.

23 Just one reason I printed it
24 out, it has to do with either choosing an
25 alternative product or avoiding genital

1 exposure to talc.

2 And let me see the exact words
3 that they use, but --

4 Q. Before you do that, do you
5 agree with the characterization that cosmetic
6 talc presents a possible risk of ovarian
7 cancer?

8 A. No, I don't think that's my
9 opinion. I think my opinion is stronger than
10 that.

11 But are you talking about my
12 causation analysis opinion or just my risk
13 assessment opinion?

14 Q. I'm asking about any opinion
15 you intend to offer in the MDL.

16 A. Okay. So I will not be giving
17 the causation analysis opinion, so that -- I
18 will take that off the table.

19 So I think my opinion is a
20 little stronger because I say that the
21 exposure to the perineal -- the talc by
22 perineal application in women increases the
23 risk. So I'm not saying it's a possible
24 risk. I'm actually -- I believe that it
25 increases the risk. And I do believe that

1 there is a association between those two
2 things, the exposure and the response, which
3 is more than a possible association, if you
4 want to use those words.

5 But my assessment that I've
6 done is not exactly the same, for example, as
7 IARC does, which is more of just a hazard
8 assessment.

9 Q. Right.

10 So I'm focusing my questions
11 now on your risk assessment as compared to
12 the documents that you've supplied us with
13 with respect to Health Canada. And if I
14 understand it correctly, are you stating that
15 your opinion with respect to the relationship
16 between cosmetic talc and ovarian cancer, you
17 believe that it is an association that is
18 stronger than a possible risk; is that
19 correct?

20 A. Well, I don't say it's a
21 possible risk; I say there is an increased
22 risk. So I think it's a different statement,
23 yes, absolutely.

24 Of course, I'm not Health
25 Canada, so, you know, they have a framework

1 upon which they make decisions, and I'm doing
2 an analysis based on what I have done. And
3 so it's not exactly the same, although some
4 of the same documents and information is
5 weighed within -- and then that's when you
6 have the issue of what Health Canada does
7 versus what they rely upon.

8 But this Taher risk assessment
9 is just one piece of information that Health
10 Canada has weighed in their assessment if you
11 read their -- their draft risk assessment.

12 Q. So the question I have about
13 the Taher risk assessment, earlier you were
14 referring to the fact that you have only seen
15 a quantitative assessment of the weight of
16 particular components of scientific evidence
17 in evaluating epidemiological studies; is
18 that correct?

19 A. So that's what I typically see,
20 yes. And I don't know that -- I've never
21 seen it. But the typical approach would be
22 to use it there as opposed to using it in the
23 context of a human health risk assessment
24 based on animal in vitro data.

25 Q. All right. Are you familiar

1 with something called the Klimisch scoring
2 system?

3 A. I don't know if I am now.
4 You'll need to show me what it is you're
5 referring to. The name doesn't ring a bell,
6 no.

7 Q. Okay. So it's not something
8 that you've used in the past?

9 A. No, not that I recall using.

10 Q. All right.

11 A. Unless it has another name, and
12 that's why I'm asking you.

13 Q. All right. So if you have
14 actually -- it's the document in front of you
15 that we've already marked as Deposition
16 Exhibit 5, I believe.

17 A. Yes.

18 Q. And that is the Taher study
19 that we were discussing and is cited by the
20 Health Canada risk assessment.

21 If you turn to page 5 -- well,
22 actually beginning on page 4, do you see
23 there is a section entitled "Literature
24 Search and Identification of Relevant
25 Nonhuman Studies"?

1 Do you see that?

2 A. Yes.

3 Q. And this is related to an
4 analysis that these authors performed on
5 potentially relevant animal and in vitro
6 studies, correct?

7 A. Yes, that is true.

8 Q. All right. And it states here
9 that "all retrieved studies were examined for
10 relevance, reliability and overall quality
11 using the Klimisch scoring system."

12 Do you see that?

13 A. Yes, I do see that. So I have
14 seen that before. I just didn't -- I didn't
15 recall it.

16 Q. Okay. And so would you agree
17 that it is possible and in fact has been done
18 in a study that you rely on to apply a
19 quantitative scoring system to animal and in
20 vitro studies, particularly in the context of
21 looking at the relationship between talc and
22 ovarian cancer?

23 A. Well, I didn't say it was
24 impossible. I said I don't believe it's
25 routine based on my experience.

1 So, yes, if they stated they've
2 done -- we'd have to pull the supplementary
3 materials out, but I recall them doing
4 scoring based on epi studies but not on
5 the -- all of the animal studies that they
6 talk about. But we can pull it out and look.
7 I could be wrong.

8 Q. Okay. Did you review the
9 supplementary material 7, 8 and 9?

10 A. Yes, I did, and we'd have to
11 pull them out because I don't recall the
12 details.

13 Q. All right. We may take a look
14 at those in a minute.

15 It talks about them classifying
16 the animal and in vitro studies into four
17 categories of reliability.

18 Do you see that?

19 A. Yes.

20 Q. So did you make any attempt,
21 when you were reviewing the various studies
22 in reaching your opinion about the potential
23 risk of talc in causing ovarian cancer, did
24 you make any attempt to separate out the
25 different pieces of evidence into categories

1 of reliability like the authors of this paper
2 have done?

3 A. I didn't do it exactly the way
4 they did it, but I certainly do do that as
5 part of my screening.

6 I told you one of the
7 characteristics or one of the assessments I
8 make is whether I believe the data is
9 reliable data that I can -- that I can use in
10 a weight of the evidence. So I make a -- and
11 when I talk about reliability, I'm talking
12 then about things such as I mentioned, peer
13 review, whether or not there is statistical
14 analysis, whether or not the study is
15 designed in a way that's consistent with
16 general principles of toxicology, control
17 groups or not control groups.

18 Those kinds of things I do -- I
19 do consider when I am assessing the use of a
20 study or not.

21 Q. Is it your testimony here today
22 that contained within your report that's
23 marked as Exhibit 4, I could find
24 categorization of reliability of each of the
25 pieces of scientific literature that you have

1 included in your weight of the evidence
2 analysis? Is that your testimony today?

3 A. No, that's not what I'm telling
4 you, no.

5 Q. Okay. So you would agree that
6 you did not -- first of all, did you develop
7 categories of reliability in which you
8 separated the particular scientific studies
9 into as part of your weight of the evidence
10 analysis?

11 A. I do look at -- I do categorize
12 studies based upon my assessment of their
13 reliability and their ability to be used to
14 answer the question I'm asking, but I -- I
15 already told you, I didn't do it the way it's
16 set out here. I didn't have these specific
17 five categories, no. That's not what I did.

18 Q. Okay. Other than the CIR 2013
19 publication, which you have said that you do
20 not find reliable and you assign little
21 weight to it, can you point me to another
22 place in Exhibit 4 where you assign a
23 specific category of weight that you have
24 given to a particular study that you include
25 in your weight of the evidence analysis?

1 A. If what you're asking me is do
2 I make a specific statement next to each
3 study that I discuss about little weight or
4 great weight, no, I don't do that, if that's
5 what you're asking me.

6 Q. Okay. As part of the
7 collection of documents that relate to Health
8 Canada that was provided to us as part of
9 your new reliance list, did you review a
10 document entitled weight of the evidence --
11 or "Weight of evidence: General principles
12 and current applications of Health Canada"?

13 A. Yes, I've seen that.
14 (Plunkett Exhibit 8 marked for
15 identification.)

16 QUESTIONS BY MS. BRANSCOME:

17 Q. All right. We will mark this
18 as Plunkett Deposition Exhibit Number 8.

19 All right. The document that I
20 just handed you that's marked as Plunkett
21 Deposition Exhibit Number 8, are you familiar
22 with that document, Dr. Plunkett?

23 A. Yep, I've seen this before.

24 Q. Is this listed among the new
25 materials that have been added to your

1 reliance list?

2 A. I believe it was, yes.

3 Q. Okay. And so for this one I
4 just want to direct your attention to the
5 conclusion section -- well, let me ask you
6 first: How does this document relate to the
7 collection of documents with respect to
8 Health Canada that you identified as relevant
9 to your opinion?

10 A. It was one of the materials
11 that they rely upon or they cite. That's the
12 reason I pulled it. It was -- I pulled
13 documents that they provided on the website
14 that were cited.

15 Q. Okay. And if you could turn to
16 page 11 of that document, there's a
17 conclusion section. The first sentence of
18 the third paragraph reads, "The given --
19 given the context-specific nature of each
20 risk assessment and the diversity of tools
21 and criteria applicable, transparent
22 documentation of the specific application of
23 the WOE approach is especially important."

24 Did I read that correctly?

25 A. Yes, you did.

1 Q. And is your understanding of
2 WOE that it is weight of evidence?

3 A. Yes, that's correct.

4 Q. Do you agree with this
5 statement?

6 A. In a regulatory context, I do
7 believe that that is true, because within the
8 regulatory context when they do the risk
9 assessment, there's a need to understand why
10 decisions are made. So, absolutely, in a
11 regulatory context, I would agree that this
12 kind of transparency is even being adopted by
13 EPA.

14 Q. And is it your opinion then
15 that a different level of transparency is
16 needed for expert testimony in court?

17 A. No, that's not what I'm saying.
18 I'm saying that's a different process. And
19 that's what part of this process is. It's
20 understanding the ability to provide a dialog
21 about what was done.

22 So as a result, this is
23 something that is common to the work that
24 I've done in the past. Even in a
25 nonlitigation context with my regulatory

1 clients, doing a risk assessment doesn't
2 necessarily involve the same level of detail
3 that a regulatory -- a regulator would apply
4 to the transparency of the assessment. Not
5 to say that it couldn't be done, but it's
6 just -- I would say it's not necessarily
7 typical.

8 Q. So this specifically refers to
9 transparent documentation.

10 Do you see that?

11 A. Yes.

12 Q. Would you agree that the report
13 that you have produced in the MDL does not
14 have documentation of the specific
15 application of the weight of evidence
16 approach?

17 MS. PARFITT: Objection.

18 Excuse me, objection. Form.

19 THE WITNESS: I disagree to an
20 extent because I did attempt to
21 provide in my report a description of
22 the methods that I used and the
23 resources that I've relied upon for a
24 discussion of how those methods are
25 used.

1 And then in addition to that,
2 I've attempted to lay out for you in
3 my report a discussion of the pieces
4 of evidence that I've relied upon,
5 including some -- for some of those --
6 that's one of the reasons I got so
7 detailed in the section on migration
8 and providing you an analysis of each
9 of the papers that I relied upon and
10 what I thought was important within
11 them that led to my -- the formation
12 of my opinions.

13 So I disagree to some extent.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. Okay. Turning back to what
16 Taher did in classifying different studies
17 into different categories of reliability.
18 Have you done that type of analysis in the
19 past where you have separated out different
20 studies into different categories of weight
21 or reliability as part of an overall
22 analysis?

23 A. Well, I do that every time I do
24 a weight of the evidence when I separate into
25 categories first based upon the type of

1 study. In other words, as I discussed many
2 times in deposition, when you're talking
3 about doing a human health risk assessment,
4 there's certain types of data that are most
5 relevant. I mean, when they use the word
6 "reliable" -- I don't know that many of these
7 studies have the same level of reliability as
8 far as peer review, but they're -- for
9 example, on the issue of migration, it's my
10 opinion that the data from the human studies
11 is a more reliable or relevant source of
12 information. And I've laid out why, because
13 of differences in the anatomy, things like
14 that, with the data.

15 Q. Are you familiar with the term
16 "binning exercise"?

17 A. Yes, I am. And that is
18 certainly something that I have used in other
19 aspects of work that I have done.

20 Q. Did you do a binning exercise
21 in rendering your opinions and what you've
22 provided to us in the context of your
23 opinions in the MDL?

24 A. Yes, that's the exercise I
25 start with. I'm binning them into human,

1 animal, mechanistic, in vitro data. That's
2 the first bins.

3 In fact, in the copper work we
4 did, that's what we did. We separated the
5 data into in vitro/only mechanistic
6 information, animal studies, did we have
7 human studies.

8 And we also looked at
9 studies -- we had a separate bin of exposures
10 like I do. I have studies that just address
11 the issue of exposure potentially.

12 So, yes, it's -- it's
13 consistent with doing that. It's --
14 essentially binning is just separating the
15 information into groups based on what
16 questions those -- those data can answer.

17 Q. Okay. Have you ever -- do you
18 ever separate them into bins based on the
19 level of weight that you would give a
20 particular study?

21 A. I do that when I'm analyzing
22 each of the studies within that group or that
23 bin. That's what I do. I give them -- in my
24 weight -- in my analysis, I weigh those
25 studies based upon my judgment on the

1 relevance, the reliability, the power of the
2 study, the statistical analysis that's done,
3 the inclusion in animal studies, in
4 particular, of controls. Those are all parts
5 of that analysis that I do. So, yes, I do do
6 that.

7 And then in -- there have been
8 exercises that I've done in the past with
9 other individuals where we may have taken a
10 yellow sticky note and put down on top of it
11 animal data with exposure information, animal
12 data without exposure information. That's
13 the process that I'm doing when I am looking
14 across the data. I'm separating those pieces
15 of data into groups and what types of
16 questions they can answer.

17 So that is consistent with what
18 I do when I do a weight of analysis approach
19 in the work that I do in both nonlitigation
20 and litigation context.

21 Q. Okay. But we have no specific
22 documentation of the different ratings that
23 you gave the various pieces of evidence that
24 you included in your weight of the evidence
25 analysis, aside from occasional references to

1 giving something less or more weight,
2 correct?

3 A. Well, I certainly -- I told you
4 I have not given numerical values that you're
5 asking me, but I've attempted to do that when
6 I have described them in groups, when I talk
7 about human versus animal versus in vitro.
8 Because I've already told you, I believe,
9 it's my opinion that certain types of
10 information are more informative than others.
11 And so the more informative it is, the more
12 weight you're giving it in -- obviously in
13 your analysis.

14 But it is a different exercise
15 than what is described here. And here I'm
16 pointing to Exhibit 8. And it's a different
17 exercise, obviously, than what a regulatory
18 body is required to do where they are trying
19 to come up with ways to increase the
20 transparency when no one can go and actually
21 talk to each of the regulators individually
22 to understand what their thinking was.

23 Q. Okay. Returning to biological
24 mechanism for a minute, why doesn't
25 inflammation generally, including chronic

1 inflammation, cause ovarian cancer?

2 A. Because it doesn't change the
3 phenotype of the cell. It has to -- the --
4 and I discuss that. You have to -- you have
5 to set up a chronic inflammatory process that
6 leads to changes within the cellular
7 phenotype to go from a cell that is -- that
8 is -- is dividing normally to a cell that
9 isn't.

10 So it's -- it's the same issue
11 that you address even in a study in animals.
12 Why do not all animals exposed to -- exposed
13 to a chemical develop tumors. It's the idea
14 that something has to be initiated beyond the
15 exposure or maybe beyond inflammation to lead
16 to the series of events.

17 And so, yes, it's recognized
18 that you can get inflammation, and
19 inflammation can go down the road in becoming
20 a carcinogenic process, or inflammation can
21 no longer -- can stay where it is. It
22 doesn't progress beyond just a chronic
23 inflammatory process.

24 Q. And so if you had a study that
25 demonstrated that a particular agent causes

1 inflammation, you would need more information
2 in order to make the conclusion that that
3 agent can in fact cause cancer, correct?

4 MR. MEADOWS: Objection.

5 THE WITNESS: You would look
6 for more informative information,
7 exactly, which is why, when I've
8 talked about the individual
9 constituents in the context of
10 consistency on mechanism for cancer,
11 I've pointed to documents where that
12 information has been discussed.

13 So like when I talk about
14 asbestos or cobalt or I point to
15 the -- for example, the IARC
16 assessment where they go through
17 that -- that discussion of the fact
18 that there's not just data showing
19 that a biologically plausible
20 mechanism may be inflammation, but
21 there's also data to show that that
22 can lead to tumor development as well.

23 QUESTIONS BY MS. BRANSCOME:

24 Q. Okay. How does talc change the
25 phenotype of the ovarian cell?

1 A. So this is one of the details
2 we don't know, other than generally it's
3 changing the phenotype to go from a normal
4 cell to a tumor cell. That is being
5 observed. When you find the presence of the
6 tumor, that is what you're observing.

7 Q. Does pure talc with no other
8 constituent components, can it change the
9 phenotype of an ovarian cell?

10 MR. MEADOWS: Objection.

11 THE WITNESS: So that's a
12 difficult question to answer with
13 certainty because of the fact that I
14 don't believe that we have assurance
15 that any of the studies are done with
16 essentially pure talc.

17 However, in the studies that
18 claim to have been done with pure
19 talc -- for example, the NTP study
20 claims to have been done with pure
21 talc. So if that is pure talc, truly
22 is, then that study is an example of
23 evidence for the chronic inflammatory
24 process leading to preneoplastic
25 lesions that are setting down the road

1 mechanism towards cancer.

2 So there are data out there.

3 The problem you have, I believe, in
4 the literature is whether or not,
5 based on the discussion that is
6 becoming apparent now with sensitivity
7 and ability to take the natural
8 product and actually determine exactly
9 what's in it, that I don't think there
10 is the ability to assure that any --
11 any of these studies with the samples
12 of talc they're using is absolutely,
13 100 percent, only platy talc. I think
14 there's -- there's some concern about
15 that. But certainly you will take --
16 you have to take what is discussed
17 within the study as evidence from what
18 they're claiming.

19 So many of the studies say we
20 used asbestos-free talc or platy --
21 pure platy talc and we got a toxic
22 response.

23 QUESTIONS BY MS. BRANSCOME:

24 Q. Would it be possible to design
25 an experiment -- and now I'm talking about an

1 in vitro or an animal experiment -- by which
2 you would expose either cells or animal to
3 talc with different constituent products to
4 identify or separate out the individual
5 effects of the components? Is that a study
6 that you could design as a toxicologist?

7 A. I think that would be difficult
8 to do, but I'm not saying impossible to do.
9 And here's the -- there are some very
10 specific considerations you'd have to put
11 into that design.

12 I would argue that some of that
13 is already available, where we have studies
14 that have looked at the dose-response effects
15 for toxicity with cobalt, with chromium, with
16 asbestos.

17 When you get to asbestos and
18 talc, it's more problematic because then the
19 question is what is -- what is it? What are
20 the specific characteristics in all the
21 different studies of exactly what the
22 asbestos was versus exactly what the talc
23 was.

24 But I think you could attempt
25 to do that, and then the question would be,

1 being able to use that data not so much to --
2 not so much to identify a dose response for a
3 certain insult, but to look at the fact --
4 look at potency differences across the
5 compounds. And then there's the issue of
6 then looking at additivity when you know you
7 have a complex mixture.

8 So that could be done, but,
9 again, it would be difficult to do based on
10 what we know about talc, being able to really
11 know that -- you would have to really be very
12 careful that what it is that you're looking
13 at is -- is not containing any of those
14 things that we unfortunately know co-occur
15 with constituents within the natural product.

16 But no one has done those
17 studies. I point that out. I haven't seen
18 that study that you're asking for. I have
19 not seen somebody do that.

20 Q. And a study like that would be
21 relevant in evaluating the potency of the
22 individual constituents and what might
23 actually be the driving factor for phenotypic
24 change, correct?

25 A. Not necessarily. I would argue

1 that we already have an answer to that by
2 looking at the data that's been collected on
3 the complex mixture itself. So the issue
4 would be why -- the question is what do you
5 gain by being able to say that we're only
6 pointing to this constituent or that
7 constituent. That isn't what is occurring.

8 What people are exposed to is
9 the complex mixture, not just each one of
10 those individual components. To me this is
11 not a case of asbestos-only exposure. This
12 is a case of exposure to consumer products
13 that are talc that may have within them at
14 any given time -- and data indicates that
15 there are substantial chance that asbestos
16 may be in -- is in certain of these products.

17 But my opinions are not
18 dependent on there being asbestos there at a
19 particular level or copper there -- or, I'm
20 sorry, cobalt there at a particular level
21 because my opinions are based on the
22 observations we have on the complex product
23 as it exists.

24 Q. And you recognize that
25 different types of talc and different talc

1 products have different constituent
2 components in different amounts, correct?

3 A. Some can. I agree with that.
4 That is true.

5 So if you're being broad, as in
6 pharmaceutical-grade versus industrial-grade
7 or chemical-grade, yeah, because they'll have
8 a purity level assigned.

9 But as far as what the -- what
10 the components are, it isn't always defined
11 even specifically within that.

12 Q. Okay. And does the presence of
13 oxidative stress in a tissue indicate that
14 cancer will develop in that tissue?

15 A. Will definitively develop?
16 Not -- I don't think you could say
17 definitively develop, but it's certainly in
18 the biologically plausible mechanism that's
19 been understood to lead to chronic
20 inflammation and also has been linked to
21 cancer.

22 So that's the issue of not
23 necessarily saying it has to be there, but it
24 certainly is something that is observed
25 routinely in cases where carcinogenesis has

1 been linked to an inflammatory response.

2 Oxidative stress is often a triggering
3 mechanism.

4 Q. Does the body have protective
5 mechanisms that limit tissue damage from
6 oxidative stress?

7 A. Yes, which is why not everybody
8 that's exposed to any particular chemical is
9 going to get cancer. Some people will
10 respond better. Some cells will respond
11 better. Some individuals in a population at
12 one time in their life may respond better.

13 Q. You would agree that in vitro
14 studies do not account for the body's natural
15 defenses outside of what exists at the
16 cellular level, correct?

17 A. Depends on the in vitro study
18 that's being done and whether or not there is
19 components added.

20 So I've seen studies done where
21 they take cells and then add extra levels of
22 glutathione to try to protect the cells from
23 certain stressors that could lead to damage,
24 but I agree with you that an isolated cell on
25 its own is a different microenvironment than

1 an intact tissue, which is a different
2 environment than an intact animal, which is
3 even different than an intact human being.
4 Yes, they're all -- you look at those levels
5 of evidence or those types of evidence
6 differently, depending upon the end points
7 you're collecting.

8 Q. And so you would give lower
9 weight to an in vitro study as compared to an
10 in vivo study, for example?

11 A. Depends on the question you're
12 asking. I would give a lot of weight if the
13 question is what do I know -- if I want to
14 try to understand the biologically plausible
15 mechanism, some of those in vitro studies are
16 some of the most important, because it's the
17 only ones that allow us to answer a question.

18 If the question is higher level
19 about what is the evidence to show that
20 there's an increased risk overall for cancer
21 or a hazard for cancer, then certainly you
22 need to have more than an in vitro study.

23 So as -- so on -- if you want
24 to layer it up, obviously, if all you had was
25 in vitro data, you'd have much less

1 confidence in the conclusions you can draw
2 unless you had some in vivo data. In vivo
3 data is going to allow you to interpret the
4 in vitro data.

5 So certainly there would be
6 more weight given in that assessment to the
7 fact that you had in vivo data.

8 Q. And so when you made the
9 statement that, for instance, you always give
10 more weight to human data, is that true, or
11 does that also depend?

12 A. Well, it depends on whether you
13 have human data. So if I have human data and
14 I have a doubt, any doubts at all, about
15 whether or not the exposure-response
16 relationship would be affected by the way the
17 animal studies are designed, then, yes, I
18 would give more weight to the human studies.

19 In a case, however, such as
20 inhalation exposure assessments where
21 there -- it's much better, actually, to do an
22 animal study where we can do a dose response
23 across different sizes of particles and
24 actually observe lesions as they develop over
25 time, which is why I love -- I love the NTP

1 93 study of interim sacrifices, looking at
2 that issue. That data is very reliable in
3 order to understand the risk of lung damage
4 as compared to a human study where we don't
5 have those serial time points, doses that are
6 defined tightly.

7 So -- and the relevance between
8 those kinds of initial lung injury in certain
9 animals versus humans match fairly well.

10 That's my problem, though, in
11 the case with the perineal exposure. I'm
12 saying to you, because of the route of
13 contact -- we need to be able to get it there
14 to the tissue -- the human data is extremely
15 important.

16 Q. So is it fair to say that in
17 some circumstances animal data gets more
18 weight than human data and in other
19 circumstances human data gets more weight
20 than animal data? It is circumstance
21 dependent?

22 A. I would put it a different way.
23 I would say in some cases animal data is
24 weighted in a similar manner to human data.
25 I don't necessarily say it would get more

1 weight, but it could if you only had one
2 crappy human study, one really badly designed
3 human study, and I had a GLP quality cancer
4 bioassay then, absolutely. I mean, IARC does
5 this. They look at that animal data and say,
6 "This one tells us -- answers the questions
7 we want to answer, and this very poorly
8 designed case series isn't going to allow us
9 to do that."

10 So you could, but I would say
11 it's more the other issue, that you look at
12 animal and human more on an equal basis if
13 the relevance and the extrapolation can be
14 done reliably.

15 And that's the question you
16 have to ask, can I extrapolate from animals
17 to humans in a reliable manner.

18 Q. Okay. Would you agree that the
19 response to cosmetic talc can vary depending
20 on tissue type in the body?

21 A. Yes, I would say that that is
22 true, whether or not there's certain
23 protective barriers in place, for example,
24 yes.

25 Q. And so in order to draw

1 conclusions based on a study of one cell
2 type's reaction to cosmetic talc to another,
3 you would need to understand the differences
4 in similarities between those two cell types,
5 correct?

6 MS. PARFITT: Objection.

7 THE WITNESS: It's a different
8 question. So you were asking me
9 about -- I didn't think you were just
10 asking about cells. I thought you
11 were asking me about like routes of
12 exposure, dermal versus inhalation.
13 Those things differ.

14 Cell types may or may not.
15 That may or may not be true. Because
16 if two cells -- two different cell
17 types in the body share similar
18 characteristics as far as the -- for
19 example, if they're both epithelial
20 cells or mesothelial cells, those type
21 of cells you would expect to respond
22 the same way.

23 But I would agree that, for
24 example, a neuronal cell versus a GI
25 cell versus a liver cell, there could

1 be differences in how they would
2 respond, yes, and so you would -- you
3 would look at those things
4 individually.

5 QUESTIONS BY MS. BRANSCOME:

6 Q. And so it's important to
7 understand the differences and the
8 similarities between the different cell types
9 before drawing conclusions using studies from
10 different cell types?

11 MS. PARFITT: Objection.

12 MR. MEADOWS: Objection.

13 THE WITNESS: I certainly think
14 you should consider the cell types
15 that are being used and whether or not
16 those cell types are ones that are
17 relevant to your risk assessment
18 question you're asking, yes.

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Okay. You would agree as a
21 toxicologist, dose is an important part of a
22 toxicological analysis of an agent, correct?

23 A. If you're doing risk, yes. If
24 you're only doing hazard, it may not be as
25 important. It depends upon the question

1 you're asking about hazard.

2 Do you want me to explain?

3 Q. I do want you to explain the
4 difference between a risk analysis and a
5 hazard analysis.

6 A. Okay. So in an initial hazard
7 analysis, if the question is, is there a
8 hazard associated with exposure, let's say,
9 by inhalation, it may not matter whether it
10 was a high dose or a low dose study. Both of
11 those can identify hazard.

12 Then you ask the question: Is
13 there a dose-response relationship? That's
14 the next step beyond hazard.

15 So hazard is -- to me is
16 identifying the end points that you're going
17 to monitor for toxicity, sort of the target
18 organs, those things, and so whether or not
19 there's a dose-response study available, it
20 wouldn't be as important.

21 But certainly when you go to
22 that next step to assess risk, you'd like to
23 be able to see whether or not there is a
24 dose-response relationship in the effect that
25 you're assessing.

1 Q. Okay. And in your -- in your
2 report, as part of your risk assessment that
3 you did in the MDL -- this is paragraph 12 on
4 page 8.

5 A. Yes, I'm there.

6 Q. Okay. You state about
7 two-thirds of the way down the paragraph that
8 "weight of the evidence methods were critical
9 to defining the literature that identified
10 the hazards of talc exposure as well as
11 defining the dose-response relationship
12 between talc exposure and the risk of adverse
13 health effects."

14 Did I read that correctly?

15 A. You did. That's correct.

16 Q. All right. Is it your view
17 that in the case you have reached an opinion
18 that defines the dose-response relationship
19 between talc exposure and the risk of ovarian
20 cancer?

21 A. It depends what you mean by
22 define. I can tell you what I mean in this
23 sentence, and maybe that would help you.

24 Q. Dr. Plunkett, it is your
25 report. And so I am asking you, using your

1 own definition of "define," have you rendered
2 an opinion that defines the dose-response
3 relationship between talc exposure and the
4 risk of ovarian cancer?

5 A. I have formed opinions about
6 the dose-response relationship generally, but
7 unfortunately -- I answered that question for
8 you earlier when you asked me, I think, about
9 is there -- I don't know if you used the word
10 "threshold," but I did.

11 So the available information
12 doesn't allow us to identify an ultimate
13 threshold, for example, in the case of women
14 exposed to talc perineally and their -- and
15 their development of ovarian cancer.

16 Instead, in defining the dose
17 response, what we can do with the data -- and
18 that is what I attempted to do. This is
19 where you look at defining the dose response
20 in the animal studies, which we can look at,
21 or defining dose response in cell studies,
22 showing that as the dose increases, the
23 hazard and the risk increase. So risk
24 actually you quantify. There's a certain
25 response at this dose and a different

1 response at the next dose, or have we
2 plateaued, that the responses are the same as
3 dose increases.

4 So that, I did do that as part
5 of my assessment, trying to define the dose
6 as far as how that linked to the responses in
7 each of the studies I looked at.

8 Q. You would agree, though, that
9 some studies did not show a dose relationship
10 between talc and ovarian cancer or the
11 clinical signs that were indicative of the
12 potential for development into ovarian
13 cancer, correct?

14 MS. PARFITT: Objection.

15 THE WITNESS: If you're talking
16 about the human data; is that what
17 you're referring to? Or are you
18 talking about all -- any of the data?

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Any of the data.

21 A. So I would disagree on the
22 animal data. I think on the animal data they
23 often -- most of the animal studies I've
24 relied upon have looked at more than one dose
25 or at least looked a no exposure versus a

1 dose, and most of them have looked at more
2 than one dose.

3 In the case of the human
4 studies, unfortunately, some of those studies
5 were not designed to be able to define dose.
6 In other words, the questions weren't asked,
7 for example, of the individuals even in the
8 prospective studies. Some of those
9 included -- did not include the information
10 collected on frequency and duration of use.

11 So if it's not collected,
12 obviously, I don't have it to look at. And
13 that's one of the limitations of human
14 epidemiological investigations, is that it
15 often is not designed appropriately to look
16 at dose response.

17 Q. Is it your opinion that there
18 are no studies looking at talc and the risk
19 of ovarian cancer in which the authors of the
20 study have concluded there was no clear
21 pattern of increased risk with dose?

22 MS. PARFITT: Objection.

23 THE WITNESS: No, that's not
24 what I've said. No. It's very
25 possible that an individual paper

1 or -- that they may make a -- an
2 author may make a statement, but I'm
3 talking about looking -- this is
4 weight of the evidence. I'm looking
5 across. And I'm saying, across the
6 data, when I look at the human data
7 versus the animal data, for example,
8 versus in vitro studies, the in vitro
9 studies and the animal studies allow
10 you to look at dose response for talc
11 toxicity.

12 The -- even the animal studies
13 allow you to look at dose response for
14 development of precancerous lesions,
15 you're on the way to cancer, for
16 example, in the NTP studies.

17 And then in the human studies,
18 some of those studies are designed
19 such that the authors could draw
20 conclusions about dose response and
21 some are not.

22 Even in some of the studies
23 where they attempted to look at dose
24 response, some of the authors indicate
25 they don't see an effect. So that is

1 true. And part of that may be driven
2 by the design of the study, the number
3 of individuals in the study, the way
4 that the questions were asked.

5 There's limitations on the way that
6 information is collected.

7 If you want to look at each
8 study, we can, but --

9 QUESTIONS BY MS. BRANSCOME:

10 Q. So my question to you, whether
11 you agree or disagree with the author's
12 conclusion, is simply that if you look at the
13 overall animal and human studies that you
14 cite in your report or have considered on
15 your reliance list that look at a potential
16 dose-response relationship for talc toxicity,
17 do some of those studies conclude that there
18 is not a dose-response relationship?

19 MS. PARFITT: Objection.

20 THE WITNESS: I disagree for
21 talc toxicity, but I would say if
22 you're going to limit it to the issue
23 of the ovarian cancer response, I
24 would agree. I have seen that in some
25 of the studies.

1 I think talc toxicity, I don't
2 know if anybody has made the
3 comment -- I would doubt it -- that
4 there is no dose response for toxic
5 effects of talc.

6 QUESTIONS BY MS. BRANSCOME:

7 Q. Okay. You discuss in your
8 report -- wait a moment. It's in
9 paragraph 58 on page 38. And I just want to
10 make sure I understood what you were citing
11 here.

12 In paragraph 58 you state that
13 "It is important to remember that
14 administration of even a single dose of talc
15 in animals has been shown to produce adverse
16 effects locally at the site of the exposure."

17 What are you referring to
18 there?

19 A. Acute doses. In other words,
20 in studies that have described installation
21 of a single dose of talc in some form into a
22 tissue, that they are observing adverse
23 responses.

24 An example of that may be
25 the -- I think it's Hamilton. Is that the

1 one where they stilled it into the ovaries
2 with a single dose?

3 Q. So these are large-dose
4 exposures?

5 A. Well, not all --

6 Q. Or are they, I should say?

7 A. I don't know that they all are,
8 no. There are -- there are -- I don't think
9 I have attempted to quantify large in this
10 sentence.

11 What I'm stating here is not an
12 issue of large versus small. It's an issue
13 of the fact that there are toxic effects with
14 single exposures. And I'm just making the
15 comment -- this has to do with hazard, right?
16 It's the idea even a single dose -- or a
17 single exposure you can get irritant,
18 inflammatory reactions at the site of
19 exposure. And that's all I'm trying to say.
20 That's why I'm citing as reviewed by EPA. I
21 believe EPA even makes a very similar
22 statement.

23 Q. Okay. Do you take into
24 account -- there are some studies for
25 which -- at least my reading of your report

1 is that you give them less weight because you
2 believe that the individuals who conducted
3 the study had been paid by either a company
4 or agencies that had some investment in the
5 outcome of the study; is that correct?

6 A. Is that my opinion?

7 Q. Yes.

8 A. For any particular study,
9 you'll need to show me what you're pointing
10 to. I do have opinions about some of the
11 work by Drs. Huncharek and Muscat, yes. I
12 think I address that specifically, and that
13 has -- that's not so much to do with my
14 weight of the evidence; that has more to do
15 with transparency and what was being
16 disseminated to the public and disseminated
17 to the FDA as far as evaluations.

18 That's a different issue than
19 the weight of -- the weight of -- the weight
20 of the evidence assessment for risk. I think
21 those were separate.

22 Q. So then I'll ask you that.

23 In doing your weight of the
24 evidence analysis for risk, have you
25 discounted the weight that you've given to

1 any particular piece of scientific evidence
2 based off of potential affiliations of the
3 authors?

4 A. I certainly did with the CIR
5 review document. I've already told you that.
6 And that's because I have evidence that shows
7 it's not just an affiliation issue, but it's
8 actually -- it's more -- it's more important
9 than that.

10 Q. Are there any other examples?

11 A. I think that's the only one
12 right now as I sit here that I can tell you
13 that I had identified as carrying little
14 weight because of an issue of either
15 authorship or input in the way it was
16 described.

17 There are certainly studies
18 within my weight of the evidence evaluation,
19 some of which were performed by industry. I
20 certainly look at that issue, but unless I
21 have -- have a reason to believe that there's
22 an inherent bias based on something I know,
23 they go into the weight of the evidence
24 without making a correction for that.

25 In many cases that I work in

1 litigation, I will find situations like the
2 situation here with Huncharek and Muscat
3 where I have, for example -- I think this
4 came up in the Risperdal litigation for me.
5 It's the idea that there was a series of
6 papers put out by an individual investigator
7 where documents that I could get access to
8 show me that indeed their analysis was not
9 done by them but it was ghostwritten by
10 somebody else. So that gives me pause,
11 although I would never have known that unless
12 I had access to internal documents.

13 So initial weight of the
14 evidence I did not discount it, but then I
15 went back and had to reevaluate the role
16 those studies played in my overall
17 assessment.

18 Q. Do you take into account in any
19 way in evaluating the weight of a study if it
20 is conducted by someone who serves as an
21 expert on behalf of the plaintiffs in the
22 active litigation?

23 A. It would be the same -- same
24 issue. I certainly consider it as part of
25 what I look at, but just like if they were an

1 expert for the defense versus an expert for
2 the plaintiff, you judge that information
3 based on what you know. And if I don't have
4 information to discount it, I will not
5 discount it.

6 But absolutely, I understand.
7 Just as people we all -- look at some of the
8 things I've published where I have said my
9 work was sponsored by the American Chemistry
10 Council. You know, people -- that's why you
11 disclose the conflicts. You put it there so
12 people can weigh it if they want, but it
13 doesn't mean you discount the work
14 automatically.

15 And so I think for any paper,
16 plaintiff, defense, whoever it is that's
17 writing it, you need to consider it based on
18 the information you have. And if you believe
19 that you have information to indicate that
20 there's some issue with the reliability of
21 the analysis, then absolutely you consider
22 that.

23 Q. So, for example, when you rely
24 on Dr. Longo's characterization of the
25 constituent components in samples that he has

1 tested, that he reports are Johnson's baby
2 powder, did you also consider the work that
3 was done by experts that have been retained
4 on behalf of the defendants to characterize
5 the components of Johnson's baby powder? Do
6 you give them equal weight?

7 A. So I haven't seen a variety of
8 the documents that you're talking about,
9 so -- because I have not worked in the
10 litigation cases that have involved asbestos
11 only. So -- which I think is where those
12 documents are.

13 In the litigation I -- in the
14 litigation I worked in, I am aware of what
15 other experts on both sides have said. I
16 don't believe I've seen an analysis from a
17 defense expert that is -- that is like
18 Dr. Longo's, at least in the litigation I've
19 worked in. Certainly I would consider that
20 and look at that if it's available, and I
21 would consider it.

22 I would point out, Dr. Longo's
23 analysis is not the piece of evidence that
24 you start with, though. You start with what
25 I discuss in the published literature first,

1 because there are published documents out
2 there in the literature that describe exactly
3 what Dr. Longo is now describing.

4 Q. What published documents are
5 those?

6 A. Those are Dr. Blount's reports
7 in 1991, which is before the litigation came
8 about, is my understanding.

9 There's also -- there's five or
10 six. I can tell you the paragraph.

11 Q. For Johnson's baby powder, I
12 would be interested in that, yes.

13 A. So I -- I'll have to look and
14 see if it's Johnson's baby powder only, but
15 certainly there is other evidence on the
16 issue of asbestos contamination and
17 specifically in talc.

18 So I -- you want me to find the
19 paragraph for you?

20 Q. Please. If you think there is
21 published literature documenting asbestos in
22 Johnson's baby powder, I would like to see
23 that.

24 A. So this is my paragraph 32.
25 And I'd have to pull each of these articles

1 out because I don't recall what each of them
2 says. But I'm pointing to Paoletti, Blount,
3 Mattenklott, Moon, Gordon, Anderson, Rohl,
4 Pooley and Rowlands, Blejer and Arlon,
5 Cralley, Millman.

6 And then I cite -- and then of
7 course the next piece of evidence is there
8 are actually documents from J&J and Imerys
9 that show detection of asbestos or
10 asbestos-like minerals in talc.

11 Q. As you sit here today, can you
12 identify which of these published articles
13 that you list in paragraph 32 relate to
14 Johnson's baby powder?

15 A. I would have to pull them to
16 answer that.

17 Q. Okay.

18 A. As I sit here, I'd have to pull
19 them. But I would refer you -- I know at
20 least some of them do based on the statement
21 I've made, but...

22 Q. So you did not make an attempt
23 in this paper to identify which products were
24 being analyzed in these specific articles.
25 It's not indicated on the face of this

1 paragraph, correct?

2 A. I don't tell you on the face,
3 but you if read the sentence I said, "When
4 commercially available, talcum powder
5 products were analyzed, including powders
6 sold by Johnson & Johnson. The data has
7 shown that the powders contained varied
8 levels" -- and I'm saying "fibers," so it's
9 just asbestos -- "including fibers that
10 stated to be asbestos."

11 So to tell you which of those,
12 I'd have to pull them. And I apologize, I
13 didn't bring them all with me.

14 Q. Have you been provided --
15 you're aware that Dr. Blount's paper does not
16 identify Johnson's baby powder in the face of
17 the article, correct?

18 A. I believe that's true. You'd
19 have to go to her deposition, I believe,
20 where she's given -- where she discusses what
21 the source of that was, and maybe even a --
22 there may even be a separate document,
23 actually, not a deposition, that was -- that
24 was in the files of Johnson & Johnson that
25 goes along with that, but I'd have to go

1 look.

2 Q. Have you reviewed Dr. Blount's
3 deposition?

4 A. I have reviewed a -- something
5 by Dr. Blount. Whether it was trial
6 testimony or deposition, I have seen
7 something, yes, that she has said regarding
8 this issue.

9 Q. To the extent that there is
10 confusion about whether or not a sample
11 tested by Dr. Blount is in fact Johnson's
12 baby powder, would you reduce the weight that
13 you give that particular piece of evidence in
14 evaluating whether asbestos has been present
15 in Johnson's baby powder?

16 MS. PARFITT: Objection. Form.

17 MR. MEADOWS: Objection.

18 THE WITNESS: I don't know
19 reduce the weight because -- because
20 there's -- there are plenty of
21 documents here that talk about that.

22 I would consider it --
23 certainly it would -- it's not so much
24 weight. It's a different bin. We'll
25 call it a bin, a different bin of

1 information. There's information on
2 talc powders generally, and then
3 there's some information that's
4 specific to certain body powders.

5 So certainly -- would I pay
6 attention if they identified it? Yes.

7 But in the statement I'm making
8 here, I'm not claiming that every one
9 of these is relating to just the
10 powder sold by Johnson & Johnson.
11 This is across the available
12 information that's public and then
13 also the information that's available
14 in the files of Johnson & Johnson.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. What is your definition of
17 asbestos?

18 A. My definition of asbestos is
19 exactly what the different documents describe
20 it typically. It's a fibrous mineral,
21 typically. It occurs in a variety of
22 different forms. Most of the times they'll
23 say "asbestos." Sometimes they'll say
24 "chrysotile." Sometimes they'll say
25 "tremolite." Sometimes they'll say

1 "anthophyllite." Those are the three most
2 common ones I see. But those are all mineral
3 forms of asbestos.

4 So just like IARC puts those
5 all within one bin, I'm putting those all in
6 one bin because they have a similar toxicity
7 profile.

8 Q. Is it your view that each of
9 the different types of asbestos has the same
10 toxicity profile?

11 A. They all have the same ability
12 to cause cancer, but they have different
13 potencies. So they do have -- there will be
14 some differences in the dose response and the
15 potency of them, but certainly they've all
16 been linked as being carcinogens by IARC.

17 And I would agree, when you
18 look at their data, there is data and
19 evidence to indicate that.

20 Q. Which type of asbestos is the
21 most potent?

22 A. For which end point? For lung
23 cancer? I believe chrysotile is. For other
24 end points, I'd have to go look. I mean,
25 chrysotile is the sharp -- is the sharp --

1 the sharded-type structure.

2 But there's data on fibrous --
3 the fiber -- the fibrous forms of asbestos
4 rather than the -- or the amphibole forms of
5 asbestos as opposed to chrysotile, which is
6 the serpentine form.

7 Q. Do you consider yourself an
8 expert in asbestos?

9 A. Not in --

10 MS. PARFITT: Objection.

11 THE WITNESS: Not the geology
12 of asbestos, no.

13 I have expertise in toxicology
14 as it relates to interpretation of the
15 data related to asbestos. I have
16 never give -- given testimony in a
17 case on asbestos, but it's something
18 I've studied in the past in my work as
19 a toxicologist, not as a testifying
20 expert.

21 QUESTIONS BY MS. BRANSCOME:

22 Q. What role does your analysis of
23 the possibility that there may be asbestos in
24 Johnson's talcum powder products play in your
25 risk assessment in the MDL?

1 A. Has to do with the fact that we
2 have a complex mixture that has multiple
3 carcinogenic substances.

4 And asbestos is important from
5 the aspect of the way that it has been
6 assessed even by regulatory bodies, the idea
7 that even very low levels of fibers pose a
8 cancer hazard and a cancer risk in
9 individuals have been shown to be
10 carcinogenic.

11 So that's what I'm saying about
12 potency of asbestos is different than potency
13 of some other carcinogens that you might look
14 at. But the importance of it is it's a
15 complex mixture, talc, body powders, a
16 complex mixture that includes constituents
17 that are known human carcinogens as well as
18 some that are -- been ranked other ways by
19 regulatory bodies.

20 Q. If Johnson's talcum powder
21 products do not contain asbestos, does that
22 change your opinion with respect to the risk
23 they pose with respect to ovarian cancer?

24 A. No, and I think that was very
25 clear if you looked at my first report. So

1 even -- there's -- I don't think in any of my
2 reports I've opined that without looking at
3 the complex mixture that we wouldn't be here.

4 In other words, I have not
5 opined that if it doesn't have -- if it
6 doesn't have asbestos, it's not a risk. I
7 have not opined that, and I don't believe
8 that, because I think there is independent
9 risk for the fact that we have a complex
10 mixture of talc that has been tested and
11 shown to be carcinogenic.

12 It's my opinion, I told you --
13 maybe it wasn't you. I may have told this
14 yesterday, I'm sorry, to Mr. Smith that I
15 believe that there is evidence to show that
16 there is a significant exposure to asbestos
17 based on the data that's been collected.

18 But certainly, you know, in
19 some -- the data has shown that in the assays
20 that have been done or the analyses that have
21 been done that you can't say that talc is
22 asbestos-free.

23 Q. Well, so --

24 A. So --

25 Q. -- the question I have

1 specifically relates to ovarian cancer.

2 Is it your view that through an
3 exposure route that is relevant for ovarian
4 cancer, that the use of Johnson's talcum
5 products involve a substantial exposure to
6 asbestos?

7 A. I believe based on the use of
8 the products that -- where the data has been
9 collected that there would be a substantial
10 exposure to asbestos, regardless of how
11 you're exposed, perineal -- perineally or by
12 inhalation.

13 Q. What is your basis for reaching
14 that conclusion?

15 A. It's looking at the number of
16 fibers that have been detected in the
17 products, in looking at the -- the widespread
18 nature of the presence of asbestos fiber --
19 asbestos in the talcum powder products and
20 the fact that even though it's at a very low
21 level by their -- their level of detection,
22 again, can't be said to be asbestos-free.

23 So regardless of whether it's
24 talc that's being applied perineally or a
25 talc that you're inhaling while you're

1 applying it perineally, the fibers are still
2 going to be present within that talc.

3 Q. Have you or anyone done an
4 analysis of the dose of asbestos to which
5 someone might be exposed perineally?

6 A. I haven't done a specific
7 calculation, no.

8 Q. Has anyone done that
9 calculation?

10 MS. PARFITT: Objection. Form.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. That you have seen?

13 MS. PARFITT: Objection.

14 THE WITNESS: I'm trying to
15 remember whether I saw that done in
16 any of the documents related to
17 Dr. Longo.

18 I don't know. I'd have to go
19 look.

20 QUESTIONS BY MS. BRANSCOME:

21 Q. Okay. So as you sit here
22 today, can you give an opinion to a
23 scientific degree of certainty, reasonable
24 degree of scientific certainty, that an
25 individual would be exposed to a dose of

1 asbestos above background through the
2 perineal use of Johnson's talcum powder
3 products?

4 MR. MEADOWS: Objection.

5 MS. PARFITT: Objection.

6 THE WITNESS: I don't think
7 that's the opinion I have formed to
8 date, but certainly the opinion I have
9 formed is that the data I have seen
10 indicates that you can't separate out
11 talc without asbestos versus talc with
12 asbestos in the information that's
13 been collected. Because there's --
14 all -- the information that's been
15 collected has shown there's no
16 evidence that asbestos-free talc is
17 available.

18 If by asking that question
19 you're trying to say that it's the
20 asbestos alone that's causing the
21 cancer, that is not my opinion. So
22 that is when the dose issue would
23 become very important for asbestos.

24 QUESTIONS BY MS. BRANSCOME:

25 Q. Okay.

1 A. So that's -- so that's a
2 different question I have not answered.

3 Q. And in reaching your opinion
4 that there is no evidence that asbestos-free
5 talc exists, you have not been provided with
6 the reports by the defense experts, including
7 Dr. Matthew Sanchez, analyzing Johnson's
8 talcum powder products for the presence or
9 absence of asbestos, correct?

10 MS. PARFITT: Objection. Form.

11 I think you're aware that the
12 MDL expert reports have not yet been
13 provided to us.

14 MS. BRANSCOME: Yeah.

15 MS. PARFITT: I'm just making a
16 point.

17 THE WITNESS: I have not seen a
18 report by Dr. Sanchez. I assume I
19 will, because typically after -- later
20 in the litigation, once all experts
21 have been deposed or revealed, I'm
22 usually given defense expert reports
23 and their deposition testimony. So I
24 expect to see that; I just haven't
25 seen it yet.

1 QUESTIONS BY MS. BRANSCOME:

2 Q. And you haven't seen it in any
3 of the cases in which you've rendered an
4 opinion, correct, not just the MDL?

5 A. Well, none of the cases that I
6 have worked in have involved the issue of
7 looking for asbestos exposure.

8 The cases I have worked on have
9 been talking about talc exposure that may
10 include asbestos as a constituent, but it
11 wasn't focused on asbestos exposure.

12 So, no, none of the cases I
13 worked on have provided testimony in that
14 area.

15 You understand what I'm saying?

16 Q. Let me just make it clear. You
17 have not, in any of the cases in which you
18 have offered opinions with respect to the
19 contents of talc, been provided with an
20 expert report or testimony by Dr. Sanchez
21 about what he did or did not find in
22 Johnson's talcum powder products with respect
23 to asbestos?

24 MS. PARFITT: Objection. Form.

25 THE WITNESS: So I can't tell

1 you that I have not. I don't recall
2 it. That's all I can say. I don't
3 recall that name.

4 QUESTIONS BY MS. BRANSCOME:

5 Q. It's certainly not something
6 you discuss in your report, correct?

7 A. No, I do not. And I don't know
8 that it's in my reliance materials. That's
9 why I'd ask you to look there, because if
10 it's in my reliance materials, then I've seen
11 it.

12 Q. Okay.

13 A. And I mean big reliance
14 material list, not my reference list.

15 Q. All right. With respect to the
16 other potential constituents of talc, have
17 you done any analysis to provide an answer as
18 to how much -- what dose of chromium, for
19 example, an individual might be exposed to
20 through the perineal use of Johnson's talcum
21 powder products over a lifetime?

22 A. No, and I have -- well, I know
23 it's a separate deposition. We discussed
24 this yesterday. No, I have not done a -- a
25 calculation of a potential dose with perineal

1 application for any of the heavy metals. So
2 the three that I've mentioned, no, I have not
3 done that calculation.

4 Q. You would agree, based on your
5 training and experience as a toxicologist,
6 that in order for an agent -- and we can talk
7 specifically about a metal -- to present a
8 risk of cancer it needs to be bioaccessible,
9 correct?

10 A. If by bioaccessible you are not
11 limiting that definition to solubilized into
12 the blood and carried systematically, yes, I
13 would agree with that. Bioaccessible meaning
14 it has to be in a form that can somehow
15 interact with the tissue, yes, I agree with
16 that. But it could be as simple as tissue
17 contact versus needing to be solubilized.

18 Q. Okay. Is silica bioaccessible?

19 A. It depends on the form of the
20 silica. So silica particles can be
21 bioaccessible if inhaled and found on the
22 surface of the lung. That can cause injury
23 at the site of the lung. So that's an
24 accessibility to that particular tissue that
25 it contacts.

1 Q. We talked earlier -- it's
2 somewhat related to bioaccessibility, but we
3 talked about the way in which different
4 particles might move specifically through the
5 genital tract in women.

6 Do you recall that?

7 A. Yes. A general discussion.

8 Q. Yes.

9 And when you testified that
10 starch and talc might not move at the same
11 rate, do you have an opinion as to which
12 might move more quickly through the tract?

13 A. I haven't formed that opinion,
14 no.

15 Q. Okay. And do both talc and
16 starch particles remain in the body for the
17 same length of time?

18 A. I haven't done an analysis to
19 see if the data tells us what the -- what the
20 differences might be. I would expect there
21 to be differences, which is what I told you
22 earlier, because I would expect the starch to
23 be able to be solubilized, where I would not
24 necessarily expect the talc to act in that
25 same manner.

1 Q. Is cornstarch capable of
2 causing an inflammatory process?

3 A. It can. It is -- but it is --
4 it's a different level of risk for
5 inflammatory responses than is talc, just by
6 its chemical nature.

7 Q. Have you done an analysis in
8 your report that examines the differences
9 between the inflammatory response that can be
10 triggered by talc as opposed to cornstarch?

11 A. I haven't analyzed inflammatory
12 response. Instead, what I've done is done a
13 comparison of what the toxicity -- the
14 differences in the toxicity potential have
15 been described in medical literature, and I
16 cite -- I have a paragraph where I cite to
17 some sources that talk about the differences
18 in the toxicity potential or biocompatibility
19 of starch versus talc.

20 Q. Now, I had a question about
21 your supplemental report that was marked as
22 Exhibit 3 to the deposition.

23 At paragraph 67...

24 A. Okay.

25 Q. You identify here six heavy

1 metals - arsenic, chromium, lead, cobalt,
2 cadmium and nickel - that in your
3 supplemental report dated August 29, 2018,
4 you say have been reported across lots of
5 talc powders.

6 Do you see that?

7 A. Are you in -- now you're in my
8 MDL report or here?

9 Q. No.

10 A. Oh, so where are you? I'm
11 sorry.

12 Q. Same report. It's the sentence
13 that begins at the bottom of page 6.

14 A. Okay. Hold on.

15 About that they have varied at
16 the levels --

17 Q. Yes. So you identify six
18 different types of heavy metals.

19 Do you see that there?

20 A. Yes, I do.

21 Q. Okay. And the question I had
22 for you was that in your report in the MDL,
23 if you look at paragraph 36 --

24 A. Yes.

25 Q. -- you identify -- you identify

1 only three heavy metals: chromium, cobalt
2 and nickel.

3 Do you see that?

4 A. Yes.

5 Q. Why did you remove three of the
6 heavy metals?

7 A. It's not so much removing.
8 Those three heavy metals that I focused on in
9 my MDL report are ones that have been talked
10 about with a similar mechanism of action as
11 far as irritation and biologic -- biologic
12 plausibility mechanism being irritation and
13 inflammation.

14 So that's why I focus on those
15 three, which may not -- which is not
16 necessarily the case for some of the others,
17 even though they're also -- have a
18 carcinogenic hazard, pose a risk.

19 Q. So in your -- as part of your
20 risk assessment that you performed in the
21 MDL, are you offering the opinion that to the
22 extent they exist in any of the Johnson
23 talcum powder products, that arsenic, lead --

24 A. Cadmium.

25 Q. -- and cadmium play any role in

1 the risk of developing ovarian cancer?

2 A. That is not an opinion that I
3 would be offering in the MDL.

4 Q. Okay. Now, you talk about
5 these heavy metals having been classified by
6 different agencies as either known probable
7 or possible human carcinogens, correct?

8 A. You're in my MDL report again?

9 Q. Oh, yes.

10 A. Okay. I'm sorry. Okay. Let
11 me get there.

12 Yeah, I do have that
13 discussion. I'm just trying to find it.

14 Q. Sure.

15 A. Okay. Yes, I'm there.

16 Q. Is it your view, based on your
17 expertise, that because a compound can cause
18 one type of cancer, it can cause all types of
19 cancer?

20 A. No, not necessarily. It
21 depends on the -- well, it depends on a
22 couple of things. It depends on what's been
23 studied. Have all types of cancer even been
24 studied. And then it also -- it also depends
25 upon, I believe, the route of exposure as

1 well. So can it get to where it could cause
2 that, could it distribute there. And then in
3 addition to that, what data has been
4 collected. Is there enough data, for
5 example, to show that there's extrapolation
6 from animals to humans in the types of tumors
7 or is it -- or if we have good human data,
8 then we would focus on the types of cancers
9 that you're seeing in humans, for example.

10 Q. Okay. But you recognize even
11 where there is complete data some compounds
12 can cause one type of cancer and they are
13 incapable of causing another type, correct?

14 MS. PARFITT: Objection. Form.

15 THE WITNESS: I don't know
16 about incapable, but I would agree
17 that you certainly would see -- you
18 could potentially see different
19 observations.

20 If you're talking about animals
21 versus humans, or are you talking
22 about --

23 QUESTIONS BY MS. BRANSCOME:

24 Q. If humans.

25 A. Based on what you had seen in

1 the animals; is that what you're asking me?

2 Q. Yes.

3 A. Yes. So, yes, there is not
4 always a one-to-one concordance. So that's
5 why -- that's why I made the comment that
6 it's important to have some human data or
7 experience, so that you can put in context
8 the data you collected in animals.

9 I would say to you there are
10 certain kinds of tumors in animals, for
11 example, that are shown to be not relevant at
12 all to human risk assessment. Like four
13 stomach tumors in rats is an example. I've
14 dealt with that one a lot.

15 Q. What types of cancer -- type or
16 types of cancer are the basis for the
17 classification of chromium as a known human
18 carcinogen by IARC?

19 A. So I have to pull it out, but I
20 believe that there may be some GI cancers and
21 maybe some skin cancers, but I'm not sure.
22 I've got it pull it out. It's been a while
23 since I've looked at it.

24 Q. Okay. Have you done an
25 analysis to evaluate whether or not the types

1 you can extrapolate with scientific basis
2 from one type of cancer cause to ovarian
3 cancer with respect to the heavy metals
4 specifically?

5 A. Well, I haven't attempted to
6 that, because I haven't attempted to define a
7 independent risk for each of those metals
8 individually.

9 The issue -- the issue I have
10 with those metals is -- there's a paragraph
11 here where I talk about pathogenesis of
12 carcinogenesis, where I talk about different
13 stages of cancer development and the fact
14 that inflammatory responses may be operating
15 at all those different stages.

16 So the issue is you have
17 potential -- you have compounds that are
18 known to produce cancer or have been shown to
19 have a potential risk of cancer. They share
20 a similar mechanism to talc, so as a result
21 of that, they factor into your risk
22 assessment as far as there being an exposure
23 to a mixture.

24 But on the issue of ovarian
25 cancer, I'm looking at the data that's been

1 collected on talc itself, which would be talc
2 with the constituents that could include the
3 metals. But certainly I'm not saying that it
4 is -- without the presence of one or the
5 other of these there would be no risk of
6 ovarian cancer. I'm not saying that either.

7 Q. So my question is, though, can
8 you point me either to scientific literature
9 directly documenting that these heavy metals
10 can cause ovarian cancer or to scientific
11 literature that enables you to extrapolate
12 from the types of cancer that they are known
13 or believed to cause to ovarian cancer?

14 A. So I -- on the issue of can I
15 point you to the data on ovarian cancer, I'd
16 have to go back. I can't answer that without
17 looking at the assessments.

18 But on the other -- second
19 question you asked me, that's the question I
20 was just trying to answer before. It's the
21 idea that regardless of where the cancer is
22 developing, the fact that these compounds
23 have the ability to stimulate similar toxic
24 responses in tissues could lead to a --
25 setting up a situation where the -- where the

1 tissue is primed for cancer development.

2 Q. And do you have --

3 A. And so that --

4 Q. Sorry.

5 A. And that has to do with the
6 basic science of carcinogenesis when you look
7 at underlying mechanisms, especially with
8 tissue contact, direct tissue contact, with
9 irritants or inflammatory processes.

10 But I would -- I am not -- I
11 have not formed the opinion, again, that with
12 or without either one of these that I would
13 expect ovarian cancer to be the target. I'm
14 saying that ovarian cancer risk is increased
15 based on exposure to talc, which includes a
16 variety of constituents.

17 Q. Okay. And do you cite anywhere
18 in your report to studies documenting -- I
19 know you said you'd need to go look at them,
20 but I'm asking if it's in your report
21 anywhere a discussion of any studies showing
22 that the particular heavy metals that you
23 cite as potential constituents of Johnson &
24 Johnson's products have been demonstrated to
25 increase a risk for ovarian cancer on their

1 own?

2 A. So, no, I haven't addressed
3 that in my report. And again, I think that's
4 inconsistent with the way I'm using these
5 data. But that's fine. I mean, no, I
6 haven't done a specific assessment of ovarian
7 cancer risk with each of those metals
8 individually.

9 Q. I would ask the same questions
10 for the different fragrance constituents that
11 you allege in your report are potential
12 carcinogens.

13 Have you done any analysis, and
14 can you point me to any scientific studies
15 that establish that those particular
16 compounds are capable of causing ovarian
17 cancer?

18 A. No, I haven't done that
19 analysis, but, again, general principles of
20 toxicology and cancer risk assessment, when
21 you look at the presence of multiple --
22 excuse me, multiple carcinogens with similar
23 mechanisms of action, you would assume in
24 your risk assessment that those risks could
25 be additive.

1 So, again, that's what I'm
2 pointing to and why I have cited the data.

3 Q. Now, you talked about -- when
4 we were discussing mechanism, you said that
5 inflammation alone is not necessarily
6 sufficient to cause cancer, correct?

7 A. Yes, I did.

8 Q. All right. Do you have
9 scientific studies that show that any of the
10 heavy metals or the fragrance constituents
11 that you identify as potential carcinogens
12 create -- generate phenotypic changes like
13 you discussed were next for the formation of
14 cancer?

15 A. I believe that data is
16 available on nickel. I need to go back and
17 look at chromium and cobalt, but I do believe
18 with nickel you'll find similar data on
19 tissue irritation and inflammatory processes.

20 Nickel is also a sensitizer, so
21 it has interaction with the immune system, so
22 I do believe that for nickel you can find
23 some of that data.

24 Q. Okay. But as you sit here
25 today, can you point me into any of that

1 that's discussed in your report?

2 A. No specific discussion other
3 than, again, all -- the IARC -- I'm citing to
4 the IARC assessments, and the IARC
5 assessments for each of those discuss
6 carcinogenesis and a biologically plausible
7 mechanism being linked to the ability of
8 these compounds to induce oxidative stress
9 and/or inflammatory processes.

10 Q. Okay. In your opinion, you
11 talk about the mixture of constituents that
12 are involved in talc.

13 Have you done any analysis to
14 look at how the different constituents
15 interact with each other?

16 A. Well, yes, that's my issue at
17 looking at underlying mechanism.

18 But are you asking me -- I
19 certainly don't have a -- the only studies
20 that I have to rely upon on the interaction
21 of the mixture is the actual studies on the
22 powders themselves, where we know that the
23 powders contain constituents other than just
24 platy talc.

25 Q. Okay. And do the constituents

1 need to have the same underlying potential
2 carcinogenic mechanism for them to have an
3 additive effect?

4 A. By general principles of
5 toxicology, yes, you look at mode -- mode of
6 action or mechanism of action before you
7 apply that additivity principle to the cancer
8 risk assessment.

9 Q. And so as you sit here, you
10 believe there have been scientific
11 documentation that nickel might operate
12 through the same biological mechanism as you
13 purport talc to operate, but you're not sure
14 about the other heavy metals or the fragrance
15 constituents; is that correct?

16 MS. PARFITT: Objection.

17 THE WITNESS: For the fragrance
18 constituents, I'd definitely have to
19 pull because I haven't looked at that
20 individual assessment in a while.

21 For these three, what I do know
22 is that they do share the ability to
23 at least induce oxidative stress.

24 What I can't recall for
25 chromium and for cobalt is whether

1 they're taking it the next step from
2 oxidative stress to inflammatory
3 process. I believe that they do, but
4 I'd have to check, whereas I know
5 nickel has been shown to lead to an
6 inflammatory process after oxidative
7 stress has been induced.

8 QUESTIONS BY MS. BRANSCOME:

9 Q. And you would agree, even more
10 than requiring an inflammatory process, you
11 would actually have to see that these
12 compounds can generate phenotypic changes,
13 correct?

14 MS. PARFITT: Objection.

15 THE WITNESS: Well, we know
16 they do because they've been shown to
17 be carcinogenic. If you've been shown
18 to be carcinogenic, you've done a
19 phenotypic change in the cell from a
20 normal cell to a cancer cell.

21 So we know they have the
22 capability to induce tumors, or
23 cancer, all three of those, at least
24 in animals if not in humans as well,
25 because two of them are known human.

1 So those two -- we'd have human data
2 to show that.

3 But on the issue of cobalt, it
4 may only be -- I need to go back and
5 look, but it may indeed just be animal
6 data.

7 QUESTIONS BY MS. BRANSCOME:

8 Q. And so your basis for that
9 would be the IARC classification?

10 Is that where I would go to
11 look if I wanted to look at it after this
12 deposition?

13 A. I'd go to the IARC reviews.
14 I'd go to those three which I believe I have
15 cited down here for you and given you where
16 to go to find them.

17 Q. Okay. You discuss in your
18 report -- and if you'd like to reference it,
19 it's paragraph 69 on page 47 -- the concept
20 of genotoxic and nongenotoxic carcinogens.

21 Do you recall that?

22 A. Yes.

23 Q. And as you sit here today, is
24 it your opinion that talc is more likely a
25 nongenotoxic carcinogen?

1 A. As the direct insult, yes. And
2 I would like to -- I would like to point out
3 that in the literature -- the reason I have
4 this paragraph here is because in the
5 literature in the past, in the area of
6 chemicals, it's been -- toxicologists have
7 attempted to put two bins, direct genotoxic
8 insult versus nondirect genotoxic. It
9 doesn't mean you can't get a genotoxic event
10 after the initiation.

11 So I want to make sure you
12 understand that. I'm not saying that there
13 is no possibility of this chemical in its --
14 in its process of inducing cancer leading to
15 indirect genotoxicity, but I'm talking about
16 the direct mechanism at the site of the cell.

17 So talc, for example, has been
18 shown to not be genotoxic in cells. And so
19 that's why I believe, then, when I look at
20 the rest of the data that fits, that it fits
21 the definition of a nongenotoxic carcinogen
22 by its initial mechanisms to induce cancer.

23 Q. Okay. And if talc is, in fact,
24 a nongenotoxic carcinogen, it would suggest
25 that there is likely a threshold dose below

1 which it does not have a carcinogenic effect,
2 correct?

3 MS. PARFITT: Objection.

4 THE WITNESS: It is possible,
5 and that's the problem. In order to
6 fully assess that, you would have to
7 have the data to prove it.

8 But that's the assumption. You
9 assume with nongenotoxic carcinogens
10 that you could identify a level where
11 you wouldn't turn on that indirect
12 mechanism. So that -- yes, that is
13 true.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. And you have not been able to
16 identify, nor can you point to, scientific
17 literature that identifies a threshold -- a
18 threshold dose for talc with respect to its
19 carcinogenic potential for ovarian cancer,
20 correct?

21 A. Not a specific dose, but I
22 think that's why I mentioned to you -- and
23 I -- I think that's why Canada, when you look
24 at their document, they talk about
25 discouraging routine use generally. So it's

1 the issue of what -- single use of a body
2 powder or an occasional use is a different
3 risk assessment than routine use.

4 So if you want to talk about
5 thresholds that way, that's very imprecise,
6 but you could do that. You can talk about
7 whether or not there -- I do believe there's
8 a different risk profile for one or two uses
9 of talc body powder versus a risk profile of
10 somebody who uses it routinely, because I
11 think that fits that threshold definition.
12 It's the idea that you have limited
13 availability for enough particles to migrate
14 to lead to the tissue toxicity that it cannot
15 be recovered from or repair.

16 Q. You're familiar with the
17 concept of the precautionary principle,
18 correct?

19 A. Yes.

20 Q. All right. And you understand
21 that Health Canada may have made
22 recommendations with respect to product usage
23 that are purely precautionary, correct?

24 MS. PARFITT: Objection. Form.

25 THE WITNESS: I disagree that's

1 what they've done, but is it possible
2 that they would do it? Any regulatory
3 agency, it's possible they could do
4 it, yes.

5 QUESTIONS BY MS. BRANSCOME:

6 Q. Do you have any information
7 with respect to Health Canada's
8 decision-making, other than what you have
9 read on the face of the documents?

10 A. That is all I have to look at
11 is what is provided on the website.

12 Q. Okay. And so the statement
13 that you think Health Canada was suggesting a
14 dose threshold by their statement of
15 discouraging routine use, you're basing that
16 entirely on what you read on the piece of
17 paper, correct?

18 MS. PARFITT: Objection. Form.

19 THE WITNESS: Well, that's what
20 they state. So, yes, I'm -- I am
21 telling you what I see on their
22 website. If that's what you're asking
23 me, yes, that is true.

24 QUESTIONS BY MS. BRANSCOME:

25 Q. Okay. Can you point me --

1 well, do you discuss -- have you looked at,
2 as part of your opinion specifically in the
3 MDL, the studies exploring a potential link
4 between asbestos and ovarian cancer? Just
5 asbestos.

6 A. Some of the studies, yes, but I
7 have not -- I have not done a separate risk
8 assessment just for asbestos by itself,
9 because I have not assumed that there is
10 asbestos-only exposure.

11 Does that make sense?

12 But I do cite -- for example, I
13 cite to some of the early literature on -- so
14 this -- I guess where this opinion comes in
15 is on hazard and warning. So in the warnings
16 I talk about when it was known that asbestos
17 was linked with cancer, because the warning
18 standard is not causation proven but the
19 identification of the potential. And so that
20 is in my report on warnings, but that is not
21 within my discussion of the weight of the
22 evidence for risk assessment of the talc
23 product.

24 Q. Okay.

25 A. Does that make sense?

1 Q. Uh-huh.

2 For example, have you rendered
3 an opinion about what dose of asbestos
4 exposure would be necessary to cause ovarian
5 cancer in an individual?

6 A. No, I have not formed that
7 opinion at this time.

8 Q. Okay. Do you have an opinion
9 about the background level of asbestos to
10 which individuals are exposed with no
11 increased risk of any type of cancer?

12 A. No, I do not have an opinion.
13 I do believe others do, but I do not.

14 Q. Okay. You may have been asked
15 some of these questions before, but I will
16 keep them brief.

17 Have you ever published any
18 articles that state that talc causes ovarian
19 cancer?

20 A. No, I have not.

21 Q. Have you ever publicly
22 expressed the opinion that talc increases the
23 risk of ovarian cancer outside of literature?

24 A. No. My work has been in the --
25 in the courtroom.

1 MS. BRANSCOME: I think we can
2 take a break.

3 VIDEOGRAPHER: We are going off
4 the record at 2:57 p.m.
5 (Off the record at 2:57 p.m.)

6 VIDEOGRAPHER: We are back on
7 the record at 3:13 p.m.

8 MS. BRANSCOME: Dr. Plunkett, I
9 have no more questions for you on
10 behalf of Johnson & Johnson, subject
11 to your counsel doing a direct of any
12 kind.

13 THE WITNESS: Sure. Thank you.

14 EXAMINATION

15 QUESTIONS BY MS. BOCKUS:

16 Q. Good afternoon, Dr. Plunkett.
17 You and I have met before. My name is Jane
18 Bockus, and as you know, I represent Imerys
19 in this case.

20 A. Yes.

21 Q. Correct?

22 I want to go back to just touch
23 briefly on a couple of issues that have
24 already been addressed.

25 Would you agree that IARC has

1 not classified any of the heavy metals that
2 you've identified in your MDL report as
3 carcinogenic to the ovary?

4 A. So the answer is I'd have to
5 look. I don't recall that, but I'd have to
6 look to confirm.

7 Q. Okay.

8 A. That's the answer I believe I
9 gave a few minutes ago, yes.

10 Q. So if I look at the IARC
11 website, then I can confirm whether or not
12 they have identified any of those as
13 carcinogenic to the ovary?

14 A. Not so much the web -- well,
15 the website or the actual documents. I think
16 I would actually point you to the actual
17 monograph --

18 Q. To the monograph.

19 A. -- because there may be
20 evidence in there of ovarian cancer as being
21 seen in studies. And I'd have to go look.

22 Q. Okay. That was not part of
23 your consideration here, correct?

24 A. So ovarian cancer is part of my
25 consideration, but I didn't -- in this part

1 of my evaluation I'm trying to -- trying to
2 describe these metals. And this is really
3 about mechanism of biologic plausibility and
4 the fact that these two things can go
5 together, and then the concept of additivity
6 is they're on hazard. The idea if you have a
7 cancer hazard generally and you have similar
8 mode of action, regardless of the tissue, you
9 would be expected to have a potential
10 additive effect when you do a risk
11 assessment.

12 So that's my use of that data,
13 which is why I didn't do a separate ovarian
14 cancer assessment for each of the each
15 constituents but just on powder.

16 Q. And you discuss that topic on
17 page 47, paragraph 68, of your report,
18 correct, the -- whether there's an additive
19 effect?

20 And you cite to Casarett and
21 Doull. I don't know if I'm pronouncing those
22 names correctly.

23 A. I'm sorry, on what page?

24 Q. I'm on page 47, paragraph 68.

25 A. Okay. Sorry. I should know

1 where it is, but...

2 Okay. I'm there, yes. Okay.

3 Yes, I do cite to a chapter in
4 Casarett and Doull, yes.

5 Q. Okay. And Casarett and Doull
6 is a resource that you cite to for a couple
7 of different toxicological principles that
8 you discuss in your -- in your report,
9 correct?

10 A. Yes, because it's one of the
11 most well-recognized textbooks that is used
12 across different either universities or
13 schools or even in regulatory agencies.

14 I would also say I cite EPA
15 2000 there. I'm not citing just Casarett,
16 but I am citing Casarett as well as an EPA
17 guidance document.

18 Q. In Casarett and Doull, do they
19 actually discuss talcum powder in Chapter 2,
20 or is it more just the concept of the
21 potential of the effects when you have two
22 different chemicals that you're exposed to at
23 once or three or four?

24 A. It's the latter. It's the --
25 because you'll notice the title is

1 "Principles of Toxicology," so it's the
2 general chapter teaching principles for risk
3 assessment and toxicology as used in risk
4 assessment.

5 Q. And whether there is an
6 additive effect of, say, talc and nickel,
7 that's something that an experiment could be
8 designed to study, correct?

9 MS. PARFITT: Objection.

10 THE WITNESS: If you're talking
11 generally for cancer and not worried
12 about the issue of ovarian cancer, if
13 you're talking about cancer, like
14 doing an inhalation experiment to look
15 what happens to the lung, that you
16 could do.

17 The problem with the animal
18 studies and ovarian cancer due to
19 perineal exposure is it's very
20 difficult to understand how you design
21 a study to expose the animals that way
22 reliably in the way that humans are
23 exposed.

24 But generally you could
25 study -- you might even be able to do

1 a genetically susceptible mouse study
2 to hurry the process along to look at,
3 but you might not be able to do it
4 through perineal exposure. You might
5 have to do it through another route
6 such as either inhalation or maybe
7 even you could -- you could look at it
8 through intraperitoneal injections,
9 for example.

10 QUESTIONS BY MS. BOCKUS:

11 Q. Well, and what the textbook
12 talks about is the fact that you need to
13 study it to find out whether the effects are
14 additive, whether the effects are something
15 that multiply the risk, you know, so that the
16 two together are greater than either one
17 alone, or do the effects offset each other
18 and reduce the risk, correct?

19 A. That is discussed there --

20 MS. PARFITT: Objection.

21 THE WITNESS: -- which is why
22 I've cited the EPA document. Because
23 the EPA document addresses the issue
24 of mixtures, and this is the issue of
25 mode of action. If you have chemicals

1 that you're looking at on the issue of
2 additivity or no effect, you will --
3 you look at that issue of how they're
4 affecting the tissue and underlying
5 mechanism.

6 But the only way to look at the
7 magnitude absolutely of how the risk
8 would change is by doing an
9 experiment. That is true.

10 QUESTIONS BY MS. BOCKUS:

11 Q. And to your knowledge, that
12 experiment has never been done; is that
13 correct?

14 A. I can't guarantee that it's
15 only been done for nickel and talc alone, but
16 I would -- I would state that based on --
17 there are studies out there that have been
18 done where they've used the body powder that
19 we know have metals -- a variety of things
20 within it that are not just platy talc, but
21 those experiments are that kind of data.

22 But as far as gathering
23 dose-response information or teasing out
24 individual components, that is not available.

25 Q. Do you agree that dose response

1 is the fundamental principle of toxicology
2 that underpins the effects that chemicals can
3 have on living organisms?

4 A. When you're talking general
5 toxicology, yes, I think it's talked about in
6 the textbook.

7 Q. And you agree that it is the
8 dose of the chemical and the pattern of
9 exposure that determines whether a chemical
10 produces an adverse effect on an organism,
11 not simply the presence of the chemical?

12 A. For a typical dose-response
13 relationship for non -- for nongenotoxic
14 events, absolutely, I would agree that is
15 probably true. And I don't mean nongeno --
16 noncancer events.

17 In the issue of cancer biology,
18 some of those issues don't hold all the time.
19 In other words, there are certain chemicals
20 and certain ways of looking at cancer risk
21 assessment where you can't assume where the
22 threshold is or identify what a safe dose
23 would be. But certainly I agree on the issue
24 of noncancer risk assessment generally, or
25 general end points of toxicity, that is true.

1 Q. And again, do you agree that in
2 general toxicology the effects that might be
3 reported at high doses will not occur at
4 lower doses if the concentration at the site
5 of action falls below the threshold for
6 toxicity?

7 A. Yes, that could -- that could
8 be possible, yes.

9 Q. And do you agree that
10 evidence-based toxicology and epidemiology
11 dictates that the dose of the chemical is the
12 critical factor when examining the risk posed
13 by a chemical, not just its presence even in
14 the human body?

15 A. I would say that's generally
16 true, yes, which is why I have attempted to
17 look at the dose-response relationship as
18 well as the prevalence of the contact.

19 Q. And with regard to the human
20 studies that you cite, would you agree that
21 none of the studies that you cite in your
22 report that have to do with migration of
23 particles within the genital tract of the
24 female involve applications to the perineum
25 or outside of the genital tract?

1 A. That is true with the exception
2 of Parmley and Woodruff, which addresses this
3 issue of --

4 MS. PARFITT: Objection.

5 THE WITNESS: Talks about the
6 issue of exposure from the outside to
7 the inside.

8 But the data that is collected
9 with the different studies they have
10 deposited at some point -- at some
11 position within the vagina, that is
12 true.

13 QUESTIONS BY MS. BOCKUS:

14 Q. And that is not how talc is
15 deposited in women who use it regularly in
16 their daily routine, correct?

17 MS. PARFITT: Objection.

18 Misstates the evidence.

19 THE WITNESS: So I would say
20 that depends on what women are doing.
21 Perineal application, for example,
22 application on the underwear, can lead
23 to contact of the vaginal opening
24 depending on the woman.

25 For example, a woman who has

1 a -- had many children has a tract
2 that is stretched. There, indeed, you
3 can have more direct contact than you
4 can with a very tight -- so I would
5 say it depends on the woman and it
6 depends on the situation.

7 But I do think it's generally
8 accepted, based on my review of the
9 literature, that there is the
10 opportunity for exposure internally
11 from perineal application.

12 QUESTIONS BY MS. BOCKUS:

13 Q. And if I understand what you
14 testified to earlier today and yesterday, you
15 don't have any data that would advise on --
16 out of the talc that is deposited in the
17 underwear, what percentage of it makes it
18 into the reproductive tract?

19 A. That's the data that's missing,
20 that is true. And unfortunately, no one has
21 done a study. It would be -- if there was a
22 way to do that, it would be interesting to do
23 that. I just don't see how you design that
24 study, especially knowing the hazard of talc
25 at this point. I think that would be a

1 difficult study to get approval for.

2 Q. And do you have an opinion as
3 to whether it is even correct that each day
4 that a woman uses talc in her underwear, that
5 some of the talc makes its way to the ovary?

6 MS. PARFITT: Objection. Form.

7 THE WITNESS: Have I -- can I
8 quantify that?

9 No, I haven't quantified it. I
10 think I got asked that earlier. I
11 can't quantify the amount that gets
12 there. Or, I'm sorry, I may have
13 misheard the start of your question.
14 I apologize.

15 QUESTIONS BY MS. BOCKUS:

16 Q. Yeah, I'm really asking: Do
17 you have an opinion as to whether it happens
18 every single time a woman applies talc to her
19 perineal area? Does some of that talc make
20 it to her ovary?

21 MR. MEADOWS: Objection.

22 MS. PARFITT: Objection.

23 THE WITNESS: I don't think I
24 stated it quite that way, but
25 certainly I think the opportunity is

1 there with every application. And of
2 course it would depend upon the amount
3 of time that the contact may be in
4 place. But the opportunity is there.

5 So, for example, if you applied
6 it to your underwear and 30 minutes
7 later you go to the bathroom, it's
8 very possible that you will have wiped
9 away, and so that that application may
10 have taken an opportunity away. But I
11 do believe that the opportunity is
12 there based on the literature I have
13 seen.

14 And so I haven't formed the
15 opinion, though, that it's absolutely
16 every time. My opinion, I think, is
17 based on the fact that I believe that
18 there is data to indicate that
19 exposure occurs, and that with
20 routine, continual habit, sort of a
21 habit exposure, that indeed that there
22 was some migration that occurs.

23 QUESTIONS BY MS. BOCKUS:

24 Q. And is it fair to say that you
25 don't have an opinion as to whether that

1 migration occurs every day, once a week, once
2 a month?

3 MS. PARFITT: Objection. Form.

4 THE WITNESS: I haven't
5 formulated my point -- my opinion
6 quite that way; however, I do believe
7 that it is something that is going to
8 happen routinely with exposure. I do
9 believe that migration is something
10 that is going on routinely with
11 application.

12 So with applications, I do
13 believe that that is, but I can't tell
14 you that this amount has migrated on
15 this particular day with this
16 particular application, no. That --
17 the data that we have collected is not
18 there to allow us to do that.

19 QUESTIONS BY MS. BOCKUS:

20 Q. How do you define the word
21 "routinely" as you're using it in that
22 answer?

23 A. So that would be the idea of
24 repeated exposures, you know, within a week,
25 within a month, within a year. So not --

1 routine to me would not be -- would not be
2 applying it once a month one month, waiting
3 six months, doing it again, and then not
4 doing it until the next year.

5 Again, it's the idea -- some
6 people may -- routine may be during the hot
7 season of the year, they're routinely getting
8 daily exposures when it's warm, and during
9 the cold weather not applying. But then the
10 next year doing -- that's a routine for them
11 and their habits based on their pattern of
12 exposure.

13 Again, we know that talc, when
14 it -- when it migrates and gets into the
15 body, we have data to show that it is -- it
16 is able to persist in the body. The fact
17 that you may have not been exposed for three
18 months because it was cold doesn't mean that
19 you -- that that changes the fact that you're
20 still at risk with additional exposures the
21 next -- the next time that that habit
22 becomes -- comes into place.

23 So I think there's multiple
24 exposure patterns that are possible, but when
25 I use routine, it's something that people are

1 doing throughout their -- a period of their
2 life. And so it would be something that
3 happens either on a weekly basis for a good
4 part of the year. I haven't defined it with
5 a particular number, though, no.

6 Q. And my question had to do with
7 out of the number of times a given woman --
8 or an average woman uses talc, what
9 percentage of the time does talc make its way
10 into her reproductive tract?

11 A. So I don't think that
12 anybody -- anybody can point to a piece of
13 data that tells you that, but, again, it's
14 based upon the anatomy, I would expect there
15 to be the potential each time it's applied.

16 And on your question on
17 routine, when I'm talking routine, I'm
18 looking at not just frequency but also
19 duration. So when I'm talking about dose,
20 it's the fact that they do it on a repeated
21 basis for a number of -- a period of years as
22 well.

23 That's what the data shows in
24 the human studies. It's not something,
25 again, that may have been done routinely for

1 one year, but it does appear to be something
2 that's done more -- longer term than that.

3 But we can't give a number. We
4 have no threshold. We don't know exactly
5 what that minimum number is.

6 Q. Do you think that the minimum
7 number is greater than a year?

8 MS. PARFITT: Objection. Form.

9 THE WITNESS: I haven't formed
10 that opinion, no.

11 QUESTIONS BY MS. BOCKUS:

12 Q. Do you think it's greater than
13 a month?

14 MR. MEADOWS: Objection.

15 THE WITNESS: Greater than a
16 month?

17 QUESTIONS BY MS. BOCKUS:

18 Q. Yes.

19 A. One month in their life?

20 Q. One month in their life, where
21 they're using it every day for a month.

22 A. So I haven't formed that
23 opinion at this point in time, but I'd say
24 it's more likely to occur when you do it more
25 than a month. But I haven't formed an

1 opinion on a set number, no. I can't --
2 can't point you a specific number.

3 I'm not doing case-specific, so
4 I've not looked at any of those pieces of
5 information for any given plaintiff.

6 Q. And I'm just trying to get the
7 threshold.

8 A. Uh-huh.

9 Q. As I understand it, that is
10 part of a toxicological evaluation, is the
11 threshold below which there's not an issue.

12 So I think you've said you
13 don't know if it's less than a year, but you
14 think it's more likely than not that it's
15 greater than one month.

16 MR. MEADOWS: Objection.

17 QUESTIONS BY MS. BOCKUS:

18 Q. Is that fair?

19 A. No, that's not exactly what I'm
20 saying. I'm saying we don't know the
21 threshold. So as a result, I'm not of the
22 opinion that it absolutely can't -- it only
23 has to be this long.

24 What I'm saying to you is per
25 general principles of toxicology and based on

1 the human data that we have, it indicates
2 that it's more frequent than just one month,
3 but I can't tell you that it's absolutely not
4 possible.

5 That's where -- I do think when
6 you're talking about those kinds of patterns,
7 that's a case-specific issue for individuals,
8 because I think that would have to be
9 considered for each individual. But
10 certainly as a toxicologist, I'm using the
11 words "routine," "repeated," "longer
12 duration," "chronic exposure." And when I
13 defined "chronic" earlier, I talked about
14 years of exposure versus just one month.

15 That would be consistent with
16 what I have said, yes, but I'm not -- I -- I
17 certainly don't want to rule out that there
18 couldn't be somebody out there that could
19 show something different, because it may very
20 well be that there are people that you can
21 identify with the presence of talc in their
22 ovaries and all of their other case-specific
23 things that could -- could make that pattern
24 a -- make someone be able to draw a
25 case-specific, reliable conclusion.

1 But that's not my role. I
2 don't do case-specific.

3 Q. And I am simply trying to get
4 the parameters of your opinions with regard
5 to the amount of talc use one would need to
6 have before you would feel comfortable --
7 well, that in your opinion would be
8 sufficient to create a toxic environment.

9 MR. MEADOWS: Objection.

10 THE WITNESS: Well, that's a
11 different question. So toxic
12 environment could be with a much
13 shorter time exposure, okay?

14 QUESTIONS BY MS. BOCKUS:

15 Q. Right.

16 A. So but if you're talking
17 about -- the opinion that I have formed has
18 to do with an increased risk of ovarian
19 cancer. So with that opinion, that's the
20 description, I believe, I was giving this
21 morning. It's the idea that the data that
22 I've seen indicates that my opinion that
23 perineal use of talc body powder products
24 increases your risk for ovarian cancer above
25 that background level that you know exists.

1 That opinion is based on data
2 that is -- is -- the supporting data would
3 indicate that it has to be a habit, routine,
4 a chronic exposure. And so as a
5 toxicologist, I've tried to put that in
6 context.

7 I don't know what else to tell
8 you. That's the opinions I have formed to
9 date.

10 Q. A chronic -- a habit, routine,
11 a chronic exposure for years?

12 A. Well, chronic --

13 MR. MEADOWS: Objection.

14 THE WITNESS: -- is defined as
15 years, typically, by a toxicologist,
16 and so that's what I -- that's what I
17 told you.

18 QUESTIONS BY MS. BOCKUS:

19 Q. Shifting to your regulatory
20 opinions, you would agree that Imerys is a
21 raw material supplier to J&J; is that
22 correct?

23 MR. MEADOWS: Objection.

24 THE WITNESS: I would call them
25 an ingredient supplier, yes.

1 QUESTIONS BY MS. BOCKUS:

2 Q. Okay. An ingredient supplier.
3 And you agree that Imerys does
4 not sell any products to the general public,
5 correct?

6 MR. MEADOWS: Objection.

7 THE WITNESS: I don't know
8 that's definitely true, but I'm not
9 aware that they do.

10 QUESTIONS BY MS. BOCKUS:

11 Q. And what Imerys supplies to
12 Johnson & Johnson is not a finished cosmetic
13 that is ready to be sold on the market,
14 correct?

15 MR. MEADOWS: Objection.

16 MS. PARFITT: Objection.

17 THE WITNESS: I don't know that
18 I can answer that except in the
19 context of Johnson & Johnson's baby
20 powder, SHOWER TO SHOWER® and Shimmer,
21 it's my understanding that Johnson &
22 Johnson mixes -- has some fragrance
23 added to the talc.

24 I don't believe Imerys does
25 that, but I don't know for sure.

1 So based on what I know -- I'm
2 telling you what I know, and I would
3 call them, again, an ingredient
4 supplier, and I would call Johnson &
5 Johnson a cosmetic manufacturer.

6 Does that answer the question?

7 QUESTIONS BY MS. BOCKUS:

8 Q. It does.

9 Would you agree that the
10 minerals that you have identified in your
11 report, that the documents that you have
12 seen, would classify their -- to the extent
13 that they are ever in the powder, that
14 they're trace ingredients?

15 MS. PARFITT: Objection.

16 MR. MEADOWS: Objection.

17 THE WITNESS: So which
18 ingredients are you referring to?

19 So some of the metals, no, are
20 not trace ingredients.

21 Are you talking about the --
22 are you talking about the -- like the
23 presence of tremolite or the presence
24 of chrysotile --
25

1 QUESTIONS BY MS. BOCKUS:

2 Q. No. No, I'm sorry. I'm
3 talking about the three metals that you
4 identify in your report. Those are trace
5 elements that are -- that are sometimes
6 detected in the studies of the -- of the
7 talc.

8 MR. MEADOWS: Objection.

9 THE WITNESS: It's not how I
10 would say it. I would say they're
11 heavy metal components that are
12 naturally occurring within the product
13 that are sometimes -- sometimes
14 detectable at levels that are reported
15 as trace based on the detection limit
16 within the analysis, but at other
17 times they're not listed as trace.
18 They're actually listed with a
19 specific amount.

20 So that's what -- how I would
21 define what I call trace. Usually
22 that's how it will be reported in the
23 lab, trace, which means below the
24 limit of quantification, but it's
25 there. You're detecting it.

1 I would agree that -- that
2 there are other descriptions of heavy
3 metals in the heavy metal literature
4 that talk about trace amounts being
5 found in -- naturally occurring in
6 food, for example, and I agree that
7 that does occur. But in the case of
8 this product, we actually have
9 often -- we actually have a -- a limit
10 that is set for acceptability in the
11 specification.

12 And so I would think it's more
13 proper to call it a level of the heavy
14 metal that is allowable by the purity
15 specifications set by the product.
16 And sometimes those levels may be
17 above, and most of the times those
18 levels are below, which is why it's
19 cleared. Because I've seen some
20 analyses where different products may
21 have been, I guess, turned away or
22 considered not acceptable based on the
23 analysis of certain types of minerals
24 or metals.

25

1 QUESTIONS BY MS. BOCKUS:

2 Q. Have you seen any studies where
3 women's blood has reflected the presence of
4 nickel or cobalt or chromium?

5 MR. MEADOWS: Objection.

6 QUESTIONS BY MS. BOCKUS:

7 Q. Who are parts of these
8 studies -- these ovarian cancer studies?

9 MR. MEADOWS: Objection.

10 THE WITNESS: The
11 epidemiological literature you're
12 asking me?

13 QUESTIONS BY MS. BOCKUS:

14 Q. Yes, ma'am.

15 A. It's possible in the Nurses'
16 Health Study that we can go to that, because
17 I know they do collect some heavy metal
18 levels. I've done that for other clients on
19 other issues.

20 Most of the others, I doubt
21 that we have heavy metal levels in blood.
22 But certainly there are levels of heavy metal
23 in blood, especially things like lead, for
24 example, that we have very limited capacity
25 to eliminate.

1 So whether or not you carry
2 around a significant body burden of a heavy
3 metal in your blood is somewhat driven by the
4 exposure pattern you get. It's something
5 that's commonly -- or can you excrete it
6 quickly or not. So...

7 Q. And are you familiar with any
8 studies that have suggested that the use of
9 body powders leads to a heavy burden of
10 nickel, chromium or cobalt in the blood?

11 A. So I have not seen such
12 analysis done, no, I have not.

13 Q. In paragraph 67 of your report,
14 which is on page 46 -- I'm sorry, on -- oh,
15 I'm sorry. Paragraph 64, I apologize.

16 A. No. No, that's fine.

17 Q. It's on page 44.

18 You cite to two abstracts --

19 A. Yes.

20 Q. -- one by Fletcher and one by
21 Fletcher and Saed.

22 Do you consider these abstracts
23 to be reliable sources of data?

24 A. They're not as reliable at all
25 as a peer-reviewed article. So there's a

1 difference in the weight you give an
2 abstract, absolutely.

3 However, knowing the papers
4 that Dr. Saed has actually published in the
5 peer-reviewed literature, I have -- I have
6 mentioned them in here because I do believe
7 that they are -- they are pieces of
8 information that are highly relevant to some
9 of the issues raised in other cellular
10 studies, and so that's why they're here. But
11 certainly I do not give them the same weight
12 as in my assessment of overall risk.

13 And I would say that I had the
14 same opinions on risk before I had these
15 studies. Because in my original reports,
16 obviously, I have gone further than risk and
17 talked about cause, and I didn't have the
18 Fletcher studies.

19 The Fletcher studies are more
20 on the issue of biologic plausibility and
21 mechanism versus being important
22 underpinnings, for example, for a hazard
23 assessment.

24 Q. Is there any way that someone
25 reading your report could tell that you

1 attribute less weight to the abstracts by
2 Saed and Fletcher just by reading your
3 report?

4 MR. MEADOWS: Objection.

5 THE WITNESS: I don't know if
6 they could or not. Hopefully they
7 would based upon where they appear in
8 the report. They're not cited a lot
9 of other places, but they certainly
10 are cited.

11 So that's why I'm here today,
12 though. You're asking me these
13 questions; I'm telling you. That's
14 how I look at these studies. That's
15 all I can say.

16 I haven't -- I haven't,
17 certainly, as I've told you, given
18 things numerical weight throughout my
19 report.

20 QUESTIONS BY MS. BOCKUS:

21 Q. Looking at paragraph 118...

22 Well, when you were preparing
23 your report, were you careful with the
24 language that you used in it to be precise
25 and accurate?

1 A. I attempted to do that. I
2 can't tell that you there isn't something in
3 here I've missed. But, yes, I read this
4 report six or seven times before I finalized
5 it, trying to make sure that the language I
6 was using was an accurate reflection of the
7 opinion I'm expressing.

8 But it's possible, if you want
9 to point to something that you want to ask me
10 about, I can tell you whether or not that was
11 something that I would change.

12 Q. So on page 77, paragraph 118 in
13 the middle of it, you say, "Based on the
14 knowledge available by the 1950s, talc body
15 powders manufactured and sold by Imerys and
16 Johnson & Johnson."

17 And that's the question that I
18 have for you.

19 A. I see what you're saying.

20 Q. Was Imerys selling anything to
21 Johnson & Johnson in the 1950s?

22 MR. MEADOWS: Objection.

23 THE WITNESS: I'm thinking.

24 It's possible they did not. That may
25 be true.

1 QUESTIONS BY MS. BOCKUS:

2 Q. Well, and actually --

3 A. You know what? When I wrote
4 this sentence, I assumed that they did, but
5 if that is not true, then certainly this
6 sentence should be just Johnson & Johnson.

7 Q. Well, earlier in your report,
8 in a footnote you indicate that Imerys began
9 supplying talc to Johnson & Johnson in 1989
10 or the late 1980s.

11 Do you remember making that
12 notation?

13 A. So let me look. So if that's
14 an inconsistency, then that should change.
15 Let me look.

16 Q. And that's all I want to know,
17 if it's an inconsistency, should it change.

18 A. If it is an inconsistency --
19 certainly if Imerys was not selling talc to
20 Johnson & Johnson in 19 -- the 1950s, then --
21 then certainly Johnson & Johnson's products
22 would not -- would not be affected by Imerys'
23 activity.

24 However, if Imerys is selling
25 talc to anyone that makes a consumer product

1 in the 1950s, then -- or a precursor company
2 to Imerys is making talc that's selling for
3 body powder to somebody other than Johnson &
4 Johnson, then that opinion would still hold.

5 So -- but I certainly agree, I
6 think I -- you're right, I think I have a
7 statement about the link between the two in
8 '89. So in that case, then certainly the --
9 the link here would be related to Johnson &
10 Johnson's products.

11 Q. Okay. Yeah.

12 A. Whether or not -- if they
13 weren't sourced from Imerys, then that's a
14 separate duty on a product, not this product.

15 Q. If you look on the bottom of
16 page 7, I think you'll see the footnote I was
17 referencing.

18 And with regard to your last
19 answer, you don't have any information as to
20 whether Imerys existed and, if it did,
21 what -- who its customers were in 1950s,
22 correct?

23 A. I don't believe I do, no.

24 MS. BOCKUS: I think that's all
25 that I have. Thank you.

1 MR. LOCKE: I've got a few
2 questions.

3 EXAMINATION

4 QUESTIONS BY MR. LOCKE:

5 Q. Doctor, my name's Tom Locke. I
6 represent the Personal Care Products Council.
7 We met a couple of times before, I think.

8 A. I apologize, I don't recall
9 your name at least. The face looked
10 familiar, though. I apologize.

11 Q. I try to maintain a low
12 profile.

13 I have relatively few
14 questions. I wanted to ask you overall about
15 your opinion.

16 Would you agree that reasonable
17 scientists can disagree with your opinion
18 that talc increases the risk of ovarian
19 cancer?

20 A. I'd say I wouldn't say it quite
21 that way. I'd say that I agree that
22 scientists can disagree on conclusions they
23 draw, depending on the -- depending on the
24 way that they have assessed.

25 So certainly based on a

1 complete assessment the way I did, then I
2 would agree that other people could come to a
3 different conclusion, absolutely.

4 So I think it depends what you
5 mean by "reasonable scientist." But I would
6 agree that individuals can look at the same
7 body of data and, based on their judgment and
8 experience, based on looking at that same
9 body of data, could come to a different
10 conclusion, yes. That's true.

11 Q. You've been involved in this
12 talc litigation for at least a couple of
13 years, right?

14 A. Yes.

15 Q. And you know that various
16 defendants have offered experts who disagree
17 with your conclusions, right?

18 A. Some of my conclusions, yes. I
19 don't know that there is somebody that's in
20 the litigation that does exactly what I do
21 across all the opinions I've expressed, but,
22 yes, certain parts of my opinions there are
23 other experts I'm aware of, yes.

24 Q. Well, they -- you're aware that
25 there are defense experts who disagree with

1 your opinion that talc increases the risk of
2 ovarian cancer; is that correct?

3 A. Yes, I -- I am aware of that
4 fact.

5 Q. And in your review of the
6 records that go back or the scientific
7 materials that go back 35 years or more,
8 you've seen that there's disagreement
9 regarding that issue; is that correct?

10 A. So what documents are you
11 referring to? Are you asking me about a
12 specific -- just the published medical
13 literature? Are you asking about documents
14 like internal company documents, reviews by
15 others? What are you asking me about?

16 Q. Well, let's focus on the
17 published medical literature.

18 There are scientists who have
19 disagreed with your opinion; is that correct?

20 MS. PARFITT: Objection.

21 THE WITNESS: I'm not aware of
22 a paper in the published medical
23 literature that has done the exact
24 assessment I have done.

25 So I am aware of the fact,

1 however, that there are individual
2 papers by scientists that, for
3 example, have concluded that there is
4 no association between exposure to
5 talc perineally and ovarian cancer,
6 yes. Individual papers, I am aware of
7 that, but that's different than what I
8 have done.

9 QUESTIONS BY MR. LOCKE:

10 Q. Let me just ask you about what
11 you were requested to do on behalf of
12 plaintiff's counsel.

13 Plaintiff's counsel asked you
14 to provide opinions related to the human
15 health hazards posed by exposure to talcum
16 powder products and how those hazards relate
17 to the regulatory requirements for marketing
18 cosmetic ingredients and cosmetic products in
19 the United States; is that correct?

20 MR. MEADOWS: Objection.

21 THE WITNESS: I didn't write
22 that, but that sounds like an accurate
23 reflection of what -- what we -- what
24 I have done at least in parts of my
25 report, yes.

1 QUESTIONS BY MR. LOCKE:

2 Q. Well, if you look at your
3 report, I think you go to part where you were
4 asked to provide -- and I just pulled it from
5 what you said.

6 A. So I did write it, I apologize.
7 It didn't sound like me.

8 Q. It started with "to provide
9 opinions related to the human health hazards"
10 and so forth, so I just wanted to make sure
11 we're clear on that.

12 A. Sure.

13 Q. So does that sound right in
14 terms of what you were asked to do?

15 A. I said I -- certainly those are
16 the kinds of things that I was definitely
17 asked to do. I was asked to do two basic --
18 two basic things, which was having to do with
19 toxicology and risk assessment, and then a
20 separate issue related to regulatory
21 concerns.

22 So, yes, those are the two
23 basic, I guess, buckets of information and
24 documents that I reviewed and opinions I've
25 expressed, and I think that's consistent with

1 what I've been doing in the litigation.

2 Q. Okay. As to that second
3 bucket, the US regulatory requirements for
4 marketing cosmetic ingredients and products,
5 that's not relevant to the scientific
6 question whether talc may cause ovarian
7 cancer; am I right?

8 A. No. I disagree with that based
9 on the fact that a company that markets a
10 cosmetic product is required to do a safety
11 assessment. And if in that safety assessment
12 issues relate to cancer or ovarian cancer and
13 the use of talc, then those two things are
14 related.

15 But I would agree that -- that
16 doing a risk assessment like I've done is a
17 separate issue from doing a safety assessment
18 for a product, because there's actually even
19 a lesser standard for an issue of looking at
20 a safety assessment for a product versus
21 actually forming the opinion that there is an
22 increased risk of cancer with exposure to
23 talc.

24 Q. Now, did IARC in 2006, did it
25 look at the US regulatory process in

1 considering whether talc may cause ovarian
2 cancer?

3 MR. MEADOWS: Objection.

4 THE WITNESS: I don't think I
5 understand what you mean. It's not a
6 US regulatory process, no, if that's
7 what you're asking me.

8 They have a -- they have a
9 discussion of what the products are,
10 which is part of the way they're sold.
11 But I don't think they're discussing
12 the duty of a company under the
13 regulatory process, no, that's a
14 separate issue.

15 QUESTIONS BY MR. LOCKE:

16 Q. So their analysis of whether
17 talc may cause ovarian cancer, that's
18 different than the analysis of whether a
19 company may have a duty, whatever that duty
20 may be?

21 MR. MEADOWS: Objection.

22 THE WITNESS: It's a different
23 process, absolutely. IARC is a
24 separate, independent body that does
25 an assessment looking at the issue of

1 cancer hazard and looking at whether
2 or not there is sufficient evidence to
3 categorize that hazard, whereas a duty
4 of a company under the regulatory
5 situation is broader than just cancer
6 hazard; it's a whole different thing.
7 It's what you do internally before you
8 market a product. Totally different.

9 And so certainly when I --
10 that's why I have separate sections in
11 my report, and that's why I even
12 have -- I've had discussions about the
13 difference between the regulatory
14 standard for warning versus the
15 assessment of risk that may be
16 required in order to start to produce
17 a -- identify a association or an
18 increased risk or even if you did a
19 causation analysis. Totally different
20 type of exercise.

21 QUESTIONS BY MR. LOCKE:

22 Q. Do you first, in that exercise,
23 look at the scientific issue of whether talc
24 may cause ovarian cancer?

25 A. Are you asking me in either of

1 these exercises?

2 Q. Well, let's say when you're
3 getting to -- you mentioned the duty to warn.
4 So if you're looking at the duty to warn, do
5 you first have to look at does talc cause
6 ovarian cancer?

7 MR. MEADOWS: Objection.

8 THE WITNESS: That's not the
9 question you asked. No. I would
10 argue, based on the regulations, if
11 you look at the standard, the question
12 is, is there evidence to indicate that
13 there is a chance, there is a
14 potential -- not that it does, but is
15 there a potential for that type of
16 hazard to be posed to consumers who
17 use the product.

18 It's a possibility versus being
19 a -- I'm taking it beyond possibility
20 when I'm doing my assessment for
21 increased risk. And I talked about
22 that this morning, and I can't
23 remember her last name. The
24 Johnson -- I apologize. But I -- with
25 Johnson & Johnson. I talked about

1 this is a different assessment and
2 different standard. It's a much lower
3 standard on cosmetics for what needs
4 to be done as far as warning.

5 Now, when a company comes and
6 initiates a safety assessment on their
7 product, before they even think about
8 what am I going to warn, they should
9 be doing a comprehensive assessment of
10 safety based on what's available
11 publicly, knowing what others have
12 reported and then what data they've
13 collected.

14 If they don't have data at all
15 on the safety of the product, then the
16 product has to say that. We don't
17 know. We do not know if this product
18 is safe. And that's one of the things
19 that is allowed under FDA -- under FDA
20 regulations as well.

21 But essentially some -- some
22 assessment must be done to understand
23 from the perspective of the company
24 that this product is safe for
25 consumers to use as -- under the

1 directions of use.

2 So in the case of this, it
3 would be a body powder being used on
4 the body surface but also perineally
5 because -- because that was an
6 exposure pattern that was understood.

7 QUESTIONS BY MR. LOCKE:

8 Q. Okay. You described two
9 different buckets. They're independent
10 assessments; is that correct?

11 MR. MEADOWS: Objection.

12 THE WITNESS: Initially that's
13 where I started, and now I'm talking
14 two different duties. There's a duty
15 to warn, but there's first a duty to
16 collect information before you market
17 it. It's your premarket safety
18 assessment.

19 QUESTIONS BY MR. LOCKE:

20 Q. Okay. I'm not actually talking
21 about the manufacturer's duty. I wanted to
22 just first address your scientific analysis.

23 That's a separate question that
24 led you to your opinion on the -- your
25 opinion that talc increases the risk of

1 ovarian cancer, correct?

2 MR. MEADOWS: Objection.

3 THE WITNESS: Yes, that's what
4 I described. And I thought you were
5 talking about duty of the company, and
6 so I apologize. I didn't mean to go
7 off on a tangent.

8 If you want to focus just on
9 the risk assessment -- is that what
10 you want to do? -- that's what I'm
11 doing.

12 QUESTIONS BY MR. LOCKE:

13 Q. No, I just want to understand,
14 those are two different things, though,
15 right?

16 A. Those are two different --
17 those are two different tasks that I
18 undertook, yes. I undertook a risk
19 assessment task to form opinions based on
20 what I can say about risk, and then I
21 separately -- and I had done this earlier on
22 the issue of warnings, looking at what do we
23 know about the product and whether or not --
24 and when did we know it, and what should
25 consumers have been warned about based on the

1 safety information that was available over
2 time.

3 Q. The risk assessment task,
4 that's what you mean by your analysis that
5 talc increases the risk of ovarian cancer?

6 A. That's correct.

7 Q. You could have stopped at that,
8 but then you performed an additional task; is
9 that right?

10 A. Well, actually, no, because the
11 first task I actually started with was the
12 regulatory task. When I first started
13 getting involved in the litigation very --
14 before I wrote my first report, one of the
15 first things I was looking at was the issue
16 of the duty of the manufacturer to provide
17 warnings.

18 And then after that, I expanded
19 that role to be an inclusion as well of a
20 causation analysis.

21 And then now I'm not doing a
22 full causation analysis in this litigation,
23 but I'm using essentially some of the same
24 information to provide you with a description
25 of a -- a health risk assessment, which was

1 also sort of -- that's a piece along the way
2 to doing a causation analysis, but it's not
3 the same.

4 Q. Your opinion regarding the
5 FDA's responsibilities and functions, that's
6 not related to your opinion that talc may
7 cause an increased risk in ovarian cancer; is
8 that correct?

9 MR. MEADOWS: Objection.

10 THE WITNESS: I don't think
11 that's true the way you're asking that
12 question, because I don't know how you
13 divorce the fact that as a -- in a
14 regulatory assessment, if I identify
15 cancer hazard, I have identified a
16 duty to warn. That's certainly
17 something that should be warned about
18 when I understand that there's not
19 only the potential, but I believe
20 there's an increased risk.

21 But I would agree with you that
22 in my report, I'm laying out for you
23 even different bodies of information
24 that -- as I step through it.

25 Does that make sense to you?

1 QUESTIONS BY MR. LOCKE:

2 Q. Not really.

3 A. I'm sorry.

4 Q. I'm talking about your
5 scientific analysis here, not your regulatory
6 analysis.

7 To do your scientific analysis,
8 you looked at scientific materials, right?

9 A. Yes, but I do the same thing
10 for my regulatory analysis. That's why I'm
11 confused. I -- to me they are connected.

12 But I would agree with you, I
13 had an analysis. Let's just talk about that,
14 my analysis on risk assessment and my
15 opinions that I've expressed. Those are laid
16 out in a separate section of my report,
17 absolutely. So we could talk about that if
18 you'd like.

19 Q. Well, I just want to
20 understand, and I think I do now, that's a
21 separate issue from your regulatory opinion?

22 A. It's not a separate issue.
23 That's where I'm having trouble with your
24 language.

25 It's a separate task because,

1 for example, I may have only been asked, but
2 I wasn't, to just describe whether or not, as
3 a human risk assessor and toxicologist, there
4 is a hazard or a risk posed by the product,
5 and I could stop there.

6 But I was asked, based on --
7 based on my experience working in the area of
8 regulatory toxicology but also on regulatory
9 issues for clients where I give advice, I was
10 asked to look at how does that scientific
11 information impact what the company should be
12 doing.

13 And so that's -- that's why I'm
14 saying you can't divorce them, because the
15 warning issue I'm talking about is intimately
16 tied into the human health risk assessment
17 results.

18 Q. So do you consider yourself
19 primarily here as a warning expert?

20 MR. MEADOWS: Objection.

21 THE WITNESS: I consider that
22 one of my roles, yes, absolutely.

23 It depends upon how individual
24 cases, individual attorneys, will --
25 will ask -- decide to use me. For

1 example, I have been used in one trial
2 to only talk about the toxicology.
3 Other trials, I've talked about
4 toxicology as well as regulatory
5 issues. So I think it just depends on
6 the case.

7 In the MDL, I am prepared,
8 however, to come to talk at a trial on
9 the regulatory system that guides
10 cosmetics as well as provide opinions
11 that talk about what are the hazards
12 of talc, what is the toxicology of
13 talc, what do -- how can you be
14 exposed to talc, that migration issue,
15 and then my opinions about whether or
16 not I believe that there is an
17 increased risk of ovarian cancer.

18 So I would be -- be prepared to
19 talk about both of those things.
20 That's why I said I do think I'm a
21 little different than some of the
22 other experts that you may encounter,
23 for example, in the defense side,
24 where someone may just do regulatory
25 or somebody may just do toxicology.

1 But I practice in both those areas in
2 my consulting practice and in my
3 experience.

4 QUESTIONS BY MR. LOCKE:

5 Q. Let me ask you a few questions
6 about your cosmetic ingredient review
7 statements, CIR.

8 We can agree to call it that,
9 right?

10 A. Yes, that's fine.

11 Q. In parts of your report, you
12 cite the CIR as an authoritative source on
13 cosmetic ingredients; is that correct?

14 A. So where are you looking at,
15 the background information on the CIR?

16 Yes, they certainly are a
17 source of information that FDA relies upon as
18 far as assessments, yes, that's true.

19 Q. Well, and on page -- or
20 paragraph 35, page 23, you cite to the CIR
21 on, for example, chemicals purportedly in
22 cosmetics. You have a footnote there.

23 A. So --

24 Q. I believe it's footnote 31.

25 A. Yes, I have looked at -- looked

1 at the CIR as a source of information because
2 many of the chemicals, many of the
3 ingredients within the fragrance of Johnson &
4 Johnson, the only available information may
5 be found within the CIR that's publicly
6 available.

7 Q. And you rely on the report of
8 Dr. Cralley; is that correct?

9 MR. MEADOWS: Objection.

10 MS. PARFITT: Objection.

11 QUESTIONS BY MR. LOCKE:

12 Q. You reference Appendix D to
13 your report. I believe if you stay on the
14 same page you'll see that, the same
15 paragraph.

16 A. I wouldn't say I rely on the
17 report of Dr. Cralley because I form my
18 opinions independent of Dr. Cralley, but
19 certainly his -- I believe if you go to his
20 reports, his report is supportive of my
21 opinions in this area.

22 Q. Did you read his report?

23 A. I have read it now, but I did
24 not read it before I -- before I formed my
25 opinions in this particular paragraph, yes.

1 Q. I'm a little confused because
2 you're citing to his report.

3 You read it or you didn't read
4 it before you wrote this paragraph?

5 A. I read it before I wrote the
6 paragraph. I didn't read it before I had
7 formed the opinion. Do you understand what
8 I'm saying?

9 I did my review of the irritant
10 chemicals independently before I looked at
11 Dr. Cralley's report. So I had formed the
12 opinion that -- of the chemicals I had
13 searched for that this is what I identified.
14 And that's what this is talking about, right?

15 I'm saying here that of the
16 more than 100 chemicals included, over
17 70 percent are compounds linked with some
18 level of irritant hazard. That was done on
19 my own.

20 Then, if you go to look at
21 Dr. Cralley's report, I cite it here because
22 it's consistent. That is, his report
23 provides support additionally for the
24 statement I'm making.

25 So I'm not relying on his

1 conclusions to make my opinion, but it's
2 certainly -- I am citing it here as it being
3 a piece of evidence that is consistent with
4 my opinions.

5 Q. Sorry, I seem to have messed up
6 my microphone. I'll try to hold it for a
7 little bit then.

8 Do you disagree with
9 Dr. Cralley's report?

10 A. I have not formed an opinion
11 that I agree or disagree. He -- with his --
12 I believe he has information that is
13 consistent with the opinion I'm expressing in
14 the sentence, however.

15 Q. And do you know that
16 Dr. Cralley repeatedly cites to the CIR as an
17 authoritative source regarding cosmetic
18 ingredients?

19 A. I don't know that he uses that
20 exact language, but he does cite to it, yes,
21 in his report. Certainly he does.

22 Q. More than 20 times, right?

23 A. That, I have not counted. I
24 can't tell you that. But he does, just like
25 I do, as a source of information when there

1 is no other source available.

2 Q. Okay. In your report you state
3 that the CIR process is administered
4 independent of the FDA.

5 But the FDA is on the CIR
6 steering committee; is that correct?

7 A. That is correct.

8 Q. You don't mention that in your
9 report, although you mention others who were
10 on the CIR steering committee, correct?

11 A. Yes, there's a paragraph where
12 I talk about others, yes.

13 Q. But you don't mention that the
14 FDA is on the steering committee?

15 A. I believe I -- I believe I've
16 been asked that question before, and I said
17 yes, but certainly in this report I don't
18 believe I state that, that is true.

19 Q. CIR solicits input from the
20 public; is that correct?

21 MS. PARFITT: Objection.

22 THE WITNESS: I would say they
23 solicit input from industry, yes.

24 QUESTIONS BY MR. LOCKE:

25 Q. Well --

1 A. But they -- and they do have a
2 public comment period, which is mainly input
3 from industry.

4 But I agree that they do -- and
5 if what you're referring to is a public
6 comment period, yes, there is that for the
7 documents.

8 Q. You can go on the website and
9 see what ingredients CIR is going to review,
10 right?

11 A. Yes, you can.

12 Q. Have you done that?

13 A. Yes, I've done it many times
14 before.

15 Q. Okay. And did you submit
16 comments on talc in 2012?

17 A. No, I did not.

18 Q. Okay. You could -- the public
19 can submit comments many times during the
20 process of an ingredient review; is that
21 correct?

22 A. There are different --
23 different stages of the draft document. Is
24 that what you're asking me? Yes, that can be
25 done.

1 Q. Well, even before it's a draft,
2 CIR is soliciting information about the
3 ingredient to include in the initial
4 materials provided to the expert panel; isn't
5 that correct?

6 A. Technically I believe that is
7 true, but I would disagree that that is
8 something that happens routinely. But I
9 would agree that -- I would say technically
10 you may be -- that is something that could
11 occur, yes, but that is not the situation,
12 for example, in the case of talc.

13 Q. Why not?

14 A. Based upon what I have seen
15 described as how the review was done, and
16 that has to do with the testimony of
17 different -- or different documents that I've
18 reviewed and the testimony of individuals
19 related to this document.

20 Q. Well, Dr. Cramer could have
21 submitted comments to the CIR regarding talc,
22 couldn't he?

23 MR. MEADOWS: Objection.

24 MS. PARFITT: Objection.

25 THE WITNESS: You'd have to ask

1 Dr. Cramer if he was aware that they
2 were reviewing it. I can't answer
3 that for Dr. Cramer.

4 But if he was aware of it,
5 certainly -- if you're aware of the
6 process going on and the timing of it,
7 certainly you can submit comments.
8 I'm not disagreeing with you on that.
9 That is true.

10 QUESTIONS BY MR. LOCKE:

11 Q. CIR publishes in advance what
12 it's going to review; isn't that correct?

13 A. What is coming up for review?

14 Q. Yes.

15 A. Yes, things that are proposed
16 for the next meeting, yes, that's true.

17 Q. And you could submit comments
18 to the first draft of the CIR report; isn't
19 that correct?

20 A. I would agree that that is
21 possible to happen, yes.

22 Q. And you can submit comments
23 before the final report is drafted, correct?

24 A. Yes, as long as it's still in
25 draft form, yes, those comments can be

1 submitted.

2 Q. And CIR meetings are open to
3 the public, right?

4 A. That is true, they are open to
5 the public, but in my experience it -- they
6 are not meetings that are heavily attended by
7 the public but indeed are -- tend to be
8 meetings attended by industry stakeholders
9 within the ingredients that are being
10 reviewed.

11 Q. You know Mr. Steinberg here.
12 He was a plaintiff's expert for a while?

13 A. I don't know him personally,
14 but I know his name and I know he was a
15 plaintiff's expert, yes.

16 Q. You know he attended the talc
17 meeting, right?

18 A. Yes, I believe he was working
19 with indus -- he works with industry, so I
20 believe indeed he did attend that meeting.

21 Q. You're not claiming he was
22 working with any industry member regarding
23 talc, are you?

24 A. That's not what I stated. I
25 know he's a consultant to the cosmetic

1 industry, so it doesn't surprise me. And I
2 believe he lives in the area, so it doesn't
3 surprise me that he attended.

4 I haven't spoken to him about
5 any of that, though, so I have no specific
6 details of that.

7 Q. Transcripts of the meeting are
8 available to the public, right?

9 A. You can download the
10 transcripts, yes.

11 Q. They're on the website?

12 A. That's what I said. You can
13 download. I'm sorry.

14 Q. Okay.

15 A. Yes, you can download them from
16 the website.

17 Q. Did you submit comments to the
18 CIR regarding talc?

19 A. No, I did not.

20 Q. Why not?

21 A. I wasn't aware of the process
22 that was going on in the draft form at the
23 time.

24 Q. Why is that?

25 A. I was not following the CIR for

1 talc at that particular time. I have a lot
2 of other clients and a lot of other issues
3 that go on on a routine basis, and I -- I
4 literally would not have time to follow every
5 assessment they do, considering that they do
6 thousands of chemicals.

7 Q. Did you know of the CIR prior
8 to your retention by plaintiff's counsel?

9 A. Yes. In fact, I -- one of the
10 journals that I receive, International
11 Journal of Toxicology, maybe, publishes many
12 of their safety assessments. So I certainly
13 am, yes.

14 I was aware -- when I was at
15 Eviron, I was aware of the existence of CIR.

16 Q. Have you ever provided prior to
17 this litigation -- and by "this litigation" I
18 mean any aspect of the talc litigation -- an
19 expert opinion on cosmetics' ingredients?

20 A. You're asking me in any other
21 litigation on a cosmetic ingredient?

22 I'm thinking back to the cases
23 I've worked on. Not as a -- not as a
24 testifying expert.

25 At Eviron, though, we worked on

1 litigation involving cosmetic ingredients,
2 thought I was not the testifying expert.

3 Q. In your report you talk about
4 the percentage of -- or the number of
5 ingredients that the CIR listed as unsafe.

6 Do you recall that?

7 A. Yes. I mean, if you want me to
8 verify the number, I need to go there. But,
9 yes.

10 Q. You don't mention that CIR has
11 put limitations on approximately 50 percent
12 of the ingredients that it has reviewed, do
13 you?

14 A. I don't mention that, but they
15 do. They have -- they have -- when they have
16 a statement about safety, they will -- they
17 will often talk about the limitations from
18 the safe use based on either concentration or
19 even maybe route of exposure, that is true.

20 Q. Why don't you do that? Why
21 didn't you include that in your report?

22 A. No particular reason. I mean,
23 the point I'm trying to make is really the
24 workload that's going on here and the
25 impossibility of the task of providing the

1 same level of review of any of these
2 ingredients as can be provided -- as was
3 provided by the IARC.

4 And so, again, that's one of
5 the comparisons I'm doing. I'm talking about
6 the difference in the time, the effort, the
7 difference in the independence of the
8 reviews. And so that -- when I'm talking
9 about, those numbers, that's what I'm
10 focusing on. I'm focusing on the fact that
11 you have so many reviews in a very short
12 period of time, with a one-expert panel, it's
13 impossible for that level of analysis and
14 review to be anywhere near what IARC panels
15 do, and also nowhere near the level of review
16 that I have done based on the number of
17 documents that I have analyzed and looked at.
18 So it's a different type of review.

19 Q. Let me ask you a few questions
20 because you have criticized the panel.

21 You would agree with that,
22 correct?

23 A. Yes. Oh, absolutely. This
24 particular analysis I have. I have made some
25 general criticisms of the overall process,

1 and then I made some specific criticisms of
2 this particular review.

3 Q. And one of your criticisms is
4 that the CIR -- I think you said two CIR
5 expert panelists had conflicts of interest;
6 is that correct?

7 A. Yes, that -- they did, that
8 were not -- that were not -- I believe not
9 understood even by Dr. Andersen at that time.
10 I think these are things brought up to him
11 that he was not aware of.

12 Q. All right. Now, you read his
13 testimony in one of the trials in California,
14 right?

15 A. Yes, that's the -- in fact,
16 that's the source of the information where
17 I'm citing to those names of those
18 individuals. I think I refer to that, his
19 trial testimony.

20 Q. And didn't he, though, say,
21 well, he didn't view it as a conflict of
22 interest because the money wasn't going to
23 them personally, it was going to their
24 organizations?

25 A. He did make that statement,

1 yes.

2 Q. And you disagree with that
3 statement?

4 A. I don't -- I mean, his
5 testimony is what it is.

6 Are you asking me do I disagree
7 that that's a conflict of interest?

8 I disagree that you shouldn't
9 disclose that as a potential conflict in the
10 documents that are produced, just like I do
11 when I write an article and I disclose that
12 I've had funding. I don't say what the
13 funding specifically paid for, but I've had
14 funding or support from this industry
15 individual or that industry individual.
16 It's -- it's something that just is about
17 transparency.

18 Q. So when you write articles, you
19 say that you've been paid a lot of money by
20 plaintiffs' lawyers?

21 MR. MEADOWS: Objection.

22 MS. PARFITT: Objection.

23 THE WITNESS: Well, I haven't
24 written an article that overlaps with
25 an issue that I've addressed in

1 plaintiffs' litigation, but I
2 certainly have given my conflict of
3 interest statements that relate to the
4 issue in the article.

5 I do that -- I've done that
6 with -- on my work -- several of my --
7 several of my assessments talking
8 about risks of pesticides. I've done
9 it with the work that I've done that
10 that's been sort of, I guess,
11 policy-type work on behalf of the
12 American Chemistry Council.

13 So absolutely I do.

14 QUESTIONS BY MR. LOCKE:

15 Q. Okay. You don't think it's
16 relevant that you receive 50 percent of your
17 money solely from plaintiffs' products
18 liability lawyers?

19 MR. MEADOWS: Objection.

20 MS. PARFITT: Objection. Form.

21 THE WITNESS: If it has nothing
22 to do with the issue that I'm
23 addressing in the paper, no, I do not
24 think that.

25 But when you're accepting money

1 from an industry or a company that has
2 to do with the issue you're looking
3 at, yes, a conflict -- a conflict of
4 interest absolutely needs to be
5 described.

6 QUESTIONS BY MR. LOCKE:

7 Q. And that would -- well, let me
8 just ask you: You're not an ethicist, are
9 you?

10 A. No, I'm not trained as an
11 ethicist.

12 Q. And you're not a lawyer, are
13 you?

14 A. Well, no, but I have passed the
15 patent bar, but I'm not trained as a lawyer.

16 Q. That doesn't make you an
17 ethicist, right?

18 A. No, it does not.

19 Q. Okay. Let's talk about one of
20 the people you criticized, Dr. Wilma
21 Bergfeld.

22 Did you know she was the first
23 woman who was the president -- to be the
24 president of the American Academy of
25 Dermatology?

1 A. No, I don't know her
2 personally, so, no, I did not know that.

3 Q. Did you investigate her at all
4 when you criticized her?

5 A. I wasn't criticizing her, I was
6 criticizing the CIR process for failing to
7 disclose the conflicts of interest of
8 individuals that were involved in their
9 assessment.

10 I certainly am not giving
11 personal criticism to either of those
12 individuals.

13 Q. You would agree that the
14 American Academy of Dermatology is a
15 reputable organization?

16 A. I haven't formed an opinion one
17 way or the other; however, I'm aware of them,
18 and certainly I know individuals that are
19 members of it, yes.

20 Q. Are those individuals reputable
21 people?

22 MS. PARFITT: Objection.

23 THE WITNESS: They are people
24 that practice medicine that certainly
25 I would go see. I mean, you're asking

1 me if I formed a very specific opinion
2 about them as individuals, and I
3 haven't done that.

4 QUESTIONS BY MR. LOCKE:

5 Q. Do you have any reason to
6 believe that the American Academy of
7 Dermatology is disreputable?

8 A. No. Again, I haven't formed an
9 opinion one way or the other. I'm aware of
10 the organization, and it certainly is one
11 that is -- has within its members a number of
12 people that I know that practice in
13 dermatology.

14 Q. Did you know that Dr. Bergfeld
15 was the first woman to be president of the
16 Cleveland Academy of Medicine?

17 A. To the what? What was the
18 first word?

19 Q. Cleveland Academy of Medicine?

20 A. No. Again, I'm not aware of
21 her CV specifically, other than what may have
22 been discussed -- it's possible her -- I know
23 her affiliation will be listed in some of the
24 documents as to where she is today, but I do
25 not know her CV and her history.

1 Q. Are you aware that she was the
2 first president -- or she was a president of
3 the American Society of Dermatopathology?

4 A. No. Same thing. If I'm not
5 aware of her CV, I wouldn't know that.

6 Q. How about that she was the
7 former chair to the FDA's drug -- FDA's
8 Dermatology and Ophthalmology Advisory
9 Committee?

10 A. Same answer. I don't know her
11 CV, so I have no knowledge.

12 Q. Is it your opinion that
13 Dr. Bergfeld was not qualified to chair the
14 CIR panel that considered talc?

15 A. I don't think I formed that
16 specific opinion. Instead, what I have --
17 the opinions I formed relate to the overall
18 makeup of the panel that failed to include
19 individuals with expertise that were -- that
20 are really key to assessing the safety of
21 talc. And that had to do with the issues of,
22 as I discuss it, epidemiology -- oh, I'm
23 sorry, I think I need to put this back --
24 period -- sorry. In the area of epidemiology
25 is one that I talked about it specifically,

1 and also gynecological -- gynecological
2 sciences on the issue of migration.

3 Q. You're not a epidemiologist,
4 are you?

5 A. Not by training. It's a tool I
6 use all the time, but I'm not an
7 epidemiologist by training.

8 Q. And panel members on the CIR,
9 they might have used the same tool that
10 you're using to form your opinion about talc,
11 correct?

12 MR. MEADOWS: Objection.

13 THE WITNESS: Based on what
14 I've reviewed from the minutes and the
15 write-up, I would disagree that that
16 is -- they have done -- they've used
17 the tools in the same way I have. I
18 disagree with that.

19 QUESTIONS BY MR. LOCKE:

20 Q. No, but I'm saying their
21 epidemiology could be the same background
22 that you have. You haven't reviewed who they
23 are, so you really don't really know.

24 MR. MEADOWS: Objection.

25 THE WITNESS: Well, I do

1 know -- I do know Dr. Klaassen, who I
2 believe was on the panel as a
3 toxicologist. He is not somebody
4 that -- he is not somebody that I
5 understand does a significant amount
6 of evaluation in risk assessment for
7 epidemiological studies. He has done
8 some of that, yes, I agree, but it's
9 different training than mine.

10 QUESTIONS BY MR. LOCKE:

11 Q. You're better qualified than he
12 is?

13 A. No, that's not what I'm saying.
14 I'm saying it's different background.

15 The question that I heard you
16 ask me, I believe, was directed towards the
17 differences in my background versus somebody
18 else's.

19 And I'm saying that I'm not
20 aware that he has the same background I do,
21 but there is not -- there was not somebody on
22 the panel that had specific expertise and
23 analysis of epidemiological studies as an
24 epidemiologist. And I think that's important
25 in this case where you're analyzing in a

1 causation analysis a wide variety of studies.

2 So I do think it's important.

3 Q. You're not a gynecological
4 oncologist, are you?

5 A. No, I'm not. But again, that
6 would have been an important expertise to
7 have on the panel when --

8 Q. And yet you formed your opinion
9 with --

10 MR. MEADOWS: Hold on.

11 MR. LOCKE: No. No. Go ahead.

12 You can ask follow-up questions
13 if you want.

14 MR. MEADOWS: You're
15 interrupting her.

16 MR. LOCKE: Well, I've got a
17 limited amount of time, and I've got
18 to keep moving.

19 MR. MEADOWS: Well --

20 MR. LOCKE: They're very long
21 answers to questions that I'm not
22 asking. So I -- you follow up if you
23 would like with your questions, but I
24 got to keep moving.

25 MR. MEADOWS: Well, I'm sorry,

1 but you're not going to be allowed to
2 interrupt her.

3 MR. LOCKE: Okay. Then we'll
4 go longer. If she's going to answer
5 questions I'm not asking, then I need
6 to go -- I need to be able to go
7 longer.

8 MR. MEADOWS: You're not going
9 to be allowed to interrupt her.
10 That's just the bottom line.

11 QUESTIONS BY MR. LOCKE:

12 Q. You're not a gynecological
13 oncologist, right?

14 A. I'm not trained as a
15 gynecologic oncologist, that is true.

16 Q. You're not a medical doctor,
17 correct?

18 A. I am not a physician, that is
19 correct.

20 Q. Let's talk about the citizens
21 petition.

22 The FDA frequently seeks
23 scientific information from cosmetic
24 manufacturers; is that correct?

25 A. First part of the question?

1 I'm sorry.

2 Q. The FDA frequently seeks
3 information, scientific information, from
4 cosmetic manufacturers; is that correct?

5 A. I don't understand what you
6 mean by "frequently seeks." They rely on
7 cosmetic manufacturers to do their own safety
8 assessments.

9 Is that what you're referring
10 to?

11 Q. Well, they ask PCPC to comment
12 on scientific issues, correct?

13 A. Yes, I would agree that that
14 interaction has happened, but that's not
15 where the responsibility lies. But I agree,
16 they have.

17 Q. I'm not asking about
18 responsibility. I'm asking: Has the FDA
19 asked cosmetic manufacturers for scientific
20 information?

21 A. Yes, they have in this case. I
22 discuss some of that, yes.

23 Q. And they do that frequently,
24 right? Not just in this case, but generally?

25 A. I can't answer that for all

1 situations. I have seen it happen before,
2 yes.

3 Q. The FDA asked, for example, for
4 then CTFA to cosponsor the 1994 workshop on
5 talc, correct?

6 A. Yes, they did.

7 Q. The FDA knew that the report
8 prepared by Dr. Huncharek and Dr. Muscat was
9 based on PCPC's retention of those
10 consultants, correct?

11 A. So what are you -- what time
12 period are you talking about?

13 Q. Well, now, there was only one
14 time that Drs. Huncharek and Muscat submitted
15 a report to the FDA regarding talc, correct?

16 A. So I need to look to confirm
17 that. Which time period are you talking
18 about?

19 Q. 2009. Citizens petition.

20 A. Oh, that is true. In the
21 citizens petition, that is true, yes. But
22 I -- but...

23 Q. I mean, it says in the letter,
24 "We're submitting a report written by Drs.
25 Huncharek and Muscat," correct?

1 A. In the cover letter from the
2 CRE?

3 Q. From -- not CRE, from PCPC.

4 A. Okay. So let -- I need to -- I
5 need to refresh my memory on the way the
6 submissions were made. I apologize.

7 Do you remember which paragraph
8 that you're referring to?

9 Q. Well, it's throughout your
10 report you're talking about the citizens
11 petition.

12 A. So it's my recollection, based
13 upon the documents that I have seen, that it
14 was not a transparent process at all times
15 that Drs. Huncharek and Muscat were being
16 identified as independent consultants and
17 were not ones that were being actually paid
18 by the industry for some of the work that
19 they did. And I think that's discussed in my
20 report.

21 Q. Well, let's break that down.

22 A. If you want me to confirm the
23 issue of the 2009 -- if you will point me to
24 where you say I discuss this, I will confirm
25 that or not.

1 Q. Well, let me break it down.

2 Citizens petition submitted in
3 2008, right?

4 A. Well, there were two: one in
5 1994 and another -- I'm sorry, 1992, and
6 another in 2008.

7 Q. Well, there are actually
8 several more than that, but let's just focus
9 on the 2008.

10 In 2008, a citizens petition
11 was submitted?

12 A. Yes, that is true.

13 Q. And PCPC responded to that
14 citizens petition in 2009, correct?

15 A. They submitted comments. Is
16 that what you're asking me? Yes, they did.

17 Q. Yes.

18 And that was a cover letter,
19 correct?

20 A. A cover letter -- that's all it
21 was was a cover letter?

22 Q. Well, attached to the cover
23 letter was a report from Drs. Huncharek and
24 Muscat?

25 A. Yes, that is true.

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1 Q. And you're not aware of any
2 other document indicating that PCPC ever
3 hired Drs. Huncharek or Muscat?

4 A. So that's where I'll need to go
5 back and look at the documents, because --
6 that I have discussed. So I need to find
7 that on my paragraph.

8 If you want to go off the
9 record for a minute so I don't waste your
10 time, I will look.

11 Q. Sure.

12 A. It's up to you. Or we can stay
13 on the record.

14 MR. LOCKE: I'm fine going off.

15 VIDEOGRAPHER: We are going off
16 the record at 4:23 p.m.

17 (Off the record at 4:23 p.m.)

18 VIDEOGRAPHER: We are back on
19 the record at 4:25 p.m.

20 QUESTIONS BY MR. LOCKE:

21 Q. The question I asked: Are you
22 aware of any other document indicating that
23 PCPC ever hired Dr. Huncharek and Muscat
24 other than for the 2009 response or
25 submission to the citizens petition?

1 A. I would have to pull this
2 document, but in paragraph 90 I make a
3 statement: A 2005 response written by
4 Dr. Muscat says -- this is not '09, this is
5 2005, and Dr. Huncharek critiqued the work of
6 Dr. Cramer, who also failed to disclose the
7 financial relation -- I'll start over.

8 Okay. So I'm sorry to repeat
9 myself, but there was a little noise.

10 You asked 2009. So the other
11 time period I have in my report in
12 paragraph 90 talks about 2005, but I'd have
13 to pull this document.

14 But I am citing to the
15 deposition of Dr. Loretz, who was a PCPC
16 employee, so I think I would need to pull
17 this in order to confirm.

18 But I see depositions of her
19 and Dr. Nicholson as talking about them
20 failing to disclose the financial
21 relationship between their work and industry.

22 Q. So if Dr. Loretz did not
23 testify that PCPC had retained Drs. Huncharek
24 and Muscat in 2005, you'd have no other
25 evidence?

1 A. I can't answer that
2 definitively, but this is what I would point
3 you to. So I'd have to pull these documents
4 to confirm, but I have -- both paragraphs 89
5 and 90 address these general issues for you,
6 but I think that's the sentence and the
7 documents that I think would be relevant.
8 But I'd have to pull them to fully answer
9 your question.

10 Q. The reason I ask the question
11 is because you frequently say "the cosmetics
12 industry" without identifying a party or a
13 person. And -- well, I'll just leave it at
14 that.

15 A. And I guess the reason I'm
16 saying I need to -- I'm questioning that it
17 doesn't have to do with PCPC is because I am
18 citing to a deposition of their employee. So
19 I need to -- I would -- to affirm it, though,
20 I'd need to -- I don't want to say that
21 100 percent the answer to your question is
22 this is the evidence, but I believe that I
23 would need to go here to confirm one way or
24 the other. But certainly I would -- this
25 raises suspicion about that for me.

1 Q. You have no evidence that PCPC
2 ever retained the Center for Regulatory
3 Effectiveness; is that correct?

4 A. I believe my evidence is hiring
5 through Imerys, but let me look to make sure
6 that is true.

7 Q. Why don't you look at page --
8 or I'm sorry, paragraph 95, page 63.

9 A. That's where I am. That's
10 where I am, so let me read what I have here
11 because it's been a while since I've read
12 this paragraph.

13 So the question is, do I have
14 in evidence this paragraph that PCPC directly
15 hired the CRE?

16 No, that is not provided by
17 this paragraph.

18 Q. Okay.

19 A. However, in this paragraph,
20 based on these documents that I'm seeing and
21 I'm -- my memory of what is discussed,
22 certainly I believe PCPC would have been
23 aware of the interaction of CRE at these time
24 points when I'm talking about this event --
25 these events.

1 Q. What evidence do you have of
2 that?

3 A. Based upon the close
4 interaction between PCPC, Imerys and Johnson
5 & Johnson throughout these time periods when
6 different actions were being taken to comment
7 or to submit information on behalf of
8 industry.

9 Q. Do you have a single document
10 you can point to or is that an assumption?

11 A. That is something I seem to
12 remember based on my review of these
13 documents, but if you need a document, I
14 would have to -- have to go and look for it.

15 Q. Sitting here today, you can't
16 recall?

17 A. I can't give you a specific
18 document as I sit here today, no.

19 MR. LOCKE: I have no further
20 questions.

21 MR. MEADOWS: Yeah, short
22 break. Maybe we're done, maybe we're
23 not.

24 VIDEOGRAPHER: We are going off
25 the record at 4:30 p.m.

1 (Off the record at 4:30 p.m.)

2 VIDEOGRAPHER: We are back on
3 the record at 4:45 p.m.

4 CROSS-EXAMINATION

5 QUESTIONS BY MS. PARFITT:

6 Q. All right. Dr. Plunkett, good
7 afternoon. I know it's been a long day.

8 Dr. Plunkett, you were asked
9 throughout the course of the day about
10 different constituents which are part of the
11 talcum powder products.

12 Do you recall those questions?

13 A. Yes.

14 Q. All right. If -- without going
15 through each and every one of different
16 constituents that we've talked about that are
17 contained or could be contained in the talcum
18 powder products, if they are present, do
19 those various constituents present and
20 provide biologically plausible evidence that
21 talcum powder products can increase the risk
22 of ovarian cancer?

23 MS. BOCKUS: Object to the
24 form.

25 THE WITNESS: Yes, which is --

1 I think I have a couple of paragraphs
2 where I talk about that issue. It has
3 to do -- there's other information as
4 well, but that is a key piece of that
5 information. And I focused on mode of
6 action and additivity. That's on
7 mechanism, biologic plausibility.

8 So the fact that you have a
9 variety of constituents that have a
10 known cancer hazard that share a mode
11 of action, that increases your
12 confidence in the biologic
13 plausibility of that relationship
14 between ovarian cancer and exposure to
15 talc body powders, yes.

16 MS. PARFITT: Thank you. I
17 have no further questions. Thank you
18 very much, Dr. Plunkett. And a happy
19 holiday to you.

20 THE WITNESS: Thank you.

21 MS. BRANSCOME: I have no
22 questions.

23 MS. BOCKUS: No questions.

24 VIDEOGRAPHER: The time now is
25 4:47 p.m. This concludes the

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1 deposition, and we are going off the
2 record.

3 (Deposition concluded at 4:47 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered
Diplomate Reporter, Certified Realtime
Reporter and Certified Shorthand Reporter, do
hereby certify that prior to the commencement
of the examination, Laura Plunkett, Ph.D.,
DABT was duly sworn by me to testify to the
truth, the whole truth and nothing but the
truth.

I DO FURTHER CERTIFY that the
foregoing is a verbatim transcript of the
testimony as taken stenographically by and
before me at the time, place and on the date
hereinbefore set forth, to the best of my
ability.

I DO FURTHER CERTIFY that I am
neither a relative nor employee nor attorney
nor counsel of any of the parties to this
action, and that I am neither a relative nor
employee of such attorney or counsel, and
that I am not financially interested in the
action.

CARRIE A. CAMPBELL,
NCRA Registered Diplomate Reporter
Certified Realtime Reporter
California Certified Shorthand
Reporter #13921
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter
#084-004229
Texas Certified Shorthand Reporter #9328
Kansas Certified Court Reporter #1715
Notary Public

Dated: 12/20/18

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it. You are signing
10 same subject to the changes you have noted on
11 the errata sheet, which will be attached to
12 your deposition.

13 It is imperative that you return
14 the original errata sheet to the deposing
15 attorney within thirty (30) days of receipt
16 of the deposition transcript by you. If you
17 fail to do so, the deposition transcript may
18 be deemed to be accurate and may be used in
19 court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
hereby certify that I have read the foregoing
pages and that the same is a correct
transcription of the answers given by me to
the questions therein propounded, except for
the corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

Laura Plunkett, Ph.D., DABT DATE

Subscribed and sworn to before me this
_____ day of _____, 20 ____.

My commission expires: _____

Notary Public

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ERRATA

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